

**The Efficacy of Acupuncture in the Treatment of Temporomandibular Joint Myofascial Pain: A Randomised Controlled Trial.**

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# **The Efficacy of Acupuncture in the Treatment of Temporomandibular Joint Myofascial Pain: A Randomised Controlled Trial.**

## **Summary**

### **Objectives**

To compare the effect of real acupuncture and sham acupuncture in the treatment of temporomandibular joint myofascial pain, in order to establish the true efficacy of acupuncture.

### **Methods**

A double blind randomised controlled trial conducted in the TMD Clinic, at the School of Dentistry, The University of Manchester. Twenty-seven patients were assigned to one of two treatment groups. Group 1 received real acupuncture treatment whilst Group 2 received a sham acupuncture intervention. Both the assessor and the patient were blinded regarding the group allocation. Baseline assessment of the outcome variables was made prior to the first treatment session, and was repeated following the last treatment.

### **Results**

The results demonstrated that real acupuncture had a greater influence on clinical outcome measure of TMJ MP than those of sham acupuncture, and the majority of these reached a level of statistical significance.

## **Conclusion**

Acupuncture had a positive influence on the signs and symptoms of TMJ MP. In addition, this study provides evidence that the Park Sham Device was a credible acupuncture control method for trials involving facial acupoints.

## **Introduction**

Myofascial pain (MP) is the most common temporomandibular disorder (TMD). To date there have been many synonyms for this condition including facial arthromyalgia, TMJ dysfunction syndrome, myofascial pain dysfunction syndrome, craniomandibular dysfunction and myofascial pain dysfunction<sup>1</sup>. Currently the preferred term, according to the Research Diagnostic Criteria (RDC/TMD) developed by Dworkin et al<sup>2</sup>, is myofascial pain (MP).

It has been suggested that between 50% and 75% of the population in all age groups have signs of MP at some time in their lives and a further 20%-25% of the population suffer symptoms but do not seek treatment. In addition, although more women seek treatment for this condition, the prevalence seems to be the same in both genders.<sup>1,3</sup> Moreover, MP has been considered to be the most common temporomandibular disorder for which TMD patients seek professional care.<sup>2,4</sup>

The aetiology of MP seems to be multifactorial, complex and largely unresolved and it has been suggested that symptoms may be due to a variety of causes, and both central and peripheral mechanisms have been implicated in the process.<sup>5,6,7,8</sup>

Although MP symptoms may vary with the stage and progress of the condition but generally one of the following five signs or/and symptoms **are present**; pain or ache in the TMJ, pain on palpation of the associated muscles, limitation or deviation of mandibular movement, joint sounds and headache. It is important to realize that headache alone and joint sounds alone are not diagnostic of MP.<sup>1</sup> Numerous treatments, either

single or in combination, have been proposed for the management of MP. A wide range of pharmacological, occlusal alteration, psychotherapeutic, and physiotherapeutic treatments have been used for the management of MP, and these are mainly aimed at the reduction of pain.<sup>9, 10, 11, 12</sup>

Acupuncture has also been reported to have a beneficial role in the management of TMD MP.<sup>13, 14, 15, 16, 17, 18,19, 20,21,22</sup> Stomach 7 (ST 7) or “Xiaguan” is an acupuncture point located inferior to the zygomatic arch, immediately anterior to the condyle of the mandible in the depression posterior to the masseter muscle. It’s location is facilitated by palpating underneath the zygomatic arch, asking the patient to open and close the jaw whilst locating the anterior aspect of the mandibular condyle, and then asking the patient to clench the jaw, in order to locate the posterior aspect of the masseter muscle. List and

Five randomized controlled trials (RCTs)<sup>15,25,26,27,28</sup> strongly suggest that acupuncture has beneficial effects similar to those of stabilization splint therapy in the management of TMJ MP. However, due to confounding methodology, lack of adequate methods of acupuncture control, and lack of validation of acupoints, the true efficacy of acupuncture has yet to be ascertained.

In a systematic review<sup>16</sup> reported that although studies suggest that acupuncture is effective in the treatment of TMJ pain and dysfunction, no trials were found that controlled for possible placebo effects of acupuncture.

Until recently attempts at providing a control group for acupuncture which provided a

similar therapeutic setting as well as being neurophysiologically inert had been unsuccessful. A recent validation study has been published which provides evidence of a method which enables adequate blinding of the participant whilst maintaining an identical therapeutic setting to that of real acupuncture. This uses what is known as a 'Park Sham Device' (PSD).<sup>29,30</sup>

The aim of this study is to compare the effect of real acupuncture and new sham acupuncture in the treatment of TMJ MP (Group I patients according to RDC/TMD<sup>2</sup>), in order to establish the true efficacy of acupuncture.

**Null Hypothesis:** there is no significant improvement in the signs and symptoms in patients receiving 'real' acupuncture, compared with those receiving a 'sham' acupuncture intervention.

## **Methods and Materials**

### **Study Design and Patient Selection**

Ethical approval was obtained through Central Manchester LREC for a double blind, randomized controlled trial conducted in the TMD Clinic, at the School of Dentistry, The University of Manchester.

### **Inclusion Criteria**

RDC/TMD was adopted for diagnosing Patients with of TMJ MP. Patients who had the condition for at least six months were considered for the trial. In addition to pain on the TMJ, all cases demonstrated two or more of the following diagnostic criteria:

- Pain on Palpation of the Associated Muscles,

- Limitation or deviation of mandibular movement,
- Intermittent joint sounds such clicking or cracking (but not crepitus)
- Headache may also be present.

**Exclusion Criteria**

- Patients with cervical trauma (whiplash/chronic cervical problems)
- Patients with systematic joint and muscle disease
- Metal allergy
- Needle phobia
- Bleeding disorders

Patients who met the inclusion criteria were informed about the study design and advised that they had equal opportunity of receiving real or sham acupuncture treatments without knowing until the trial had ended. Possible risks of acupuncture treatment were explained. They were informed that they could stop participating in the study at any time. A written informed consent was obtained by each patient who entered the trial.

35 patients who were referred to the TMD Unit, School of Dentistry, The University of Manchester were assessed for suitability and 27 patients met the inclusion criteria. Adult subjects were recruited over a period of 5 weeks (June –July 2003). They were assigned to one of two treatment groups. Group 1 received real acupuncture treatment whilst Group 2 received a sham acupuncture intervention. A computerized randomization programme was used to generate group allocation of patients, which

were concealed in opaque envelopes by a person not involved with the study. Both the assessor and the patient were blinded regarding the group allocation. However, the clinician performing either intervention was aware of the group affiliation. Patients were advised to continue any other ongoing treatment such as medication or splint therapy for the condition at the same level as usual. They were, however, requested not to commence any other new intervention. Baseline assessment of the outcome variables was made prior to the first treatment session, and was repeated following the last treatment.

#### ***The Sham Acupuncture Needle***

The sham acupuncture needle looks exactly like a real needle, but is blunt and free to slide within its handle so that, when pressed, it telescopes into the handle rather than penetrating the skin (Fig 1). This needle is the same size as the real one (0.35 mm x 70mm) and it is stainless steel and manufactured by Dong Bang Acupuncture Inc, Korea.

#### ***Park Sham Device (PSD)***

Both the blunt 'sham' acupuncture needles and the 'real' needles are applied through a holder (PSD) (Fig 2) which is held in place on the skin by a self adhesive pad.

#### **Initial Assessment and Assignment**

Patient details and assessment of baseline outcome measures were performed and documented by an experienced clinician involved in the TMD clinic in accordance



with standards described by Gray et al.<sup>1</sup>The following outcome measures were assessed at baseline and completion of the study:

- **Patient Functional Perspective.** 10cm Visual Analogue Scale (VAS) functional scale was used. A reading of 0 cm was equal no functional impairment e.g. in eating, talking, or sleeping. A reading of 10cm meant maximal functional impairment, severely limiting the subject in all such functions.
- **Pain Intensity.** A 10cm VAS was used 0cm = no pain, 10cm = worst pain imaginable.<sup>31</sup>
- **Pain Distribution.** The areas in which the patients reported having experienced pain in relation to the TMD MP was recorded on a head chart. These were divided into three sections: Area 1: The main area surrounding the TMJ; Area 2: The lower area including the neck and shoulder; Area 3: The upper area including the eye and temporal regions (Fig 3).
- **Incisor opening and lateral movement measurement.** These are reliable and valid methods for documenting and monitoring status of TMD patients.<sup>32</sup> Maximal opening and pain free opening were measured in millimeters using Vernier style bite gauge. Both inter and intra-operator reliability of using this device for such measurements has been established.<sup>33</sup>
- **Muscle tenderness.** The right and left masseters were palpated for the presence of tenderness. Right and left lateral pterygoid tenderness was recorded by its response to resisted vertical and lateral movements.<sup>1</sup>
- **TMJ tenderness.** The presence of tenderness was detected by palpation of the

lateral and intra-auricular palpation of the right and left TMJs.

- **Headaches.** The patient was subjectively asked to report any presence of "nonspecific" headaches in connection with TMD MP.
- **Deviation.** This sign is could be an indication of spasms in the masticatory muscles. This was noted as any observable deviation of jaw movement from a vertical straight line whilst opening and closing the mouth.
- **TMJ sounds.** Clicking was detected by lateral and intra auricular palpation of the TMJ, as well as with a stereo-stethoscope. The apparatus provides a method of accurately and reproducibly detecting TMJ sounds and determining whether they emanate from the left, right or are bilateral.<sup>1</sup>

Improvement or elimination of the above mentioned outcome measures were considered as a positive treatment outcome.

#### **Treatment Procedure**

Each patient received six acupuncture treatments bilaterally at ST 7 (Fig 4). These took place over a three week period and were administered by one of the authors who was experienced in the use of acupuncture.

After ST 7 was located a circular indentation was made into the skin to mark the using the end of the guide tube. The area was then disinfected with alcohol and the acupuncture needle (real or sham) was then applied to the centre of the circular mark, using a sterile technique, perpendicular to the skin, through the PSD.

#### ***Needling Technique***

The 'real' acupuncture group received the true penetrative needle, i.e. with a sharp point. This needle was inserted 6mm-12mm into the skin until resistance or pain were felt. For the 'sham' acupuncture group, the blunt needle end only touched the skin, and the handle was able to slide 12mm down the needle. The needle was retained in position for twenty minutes in both groups with manual stimulation by tapping the needle every five minutes for ten seconds. On removal of the needle, pressure was immediately applied to the skin, using a cotton bud, for ten seconds, or until any bleeding had ceased. The acupuncture site was then re-examined and the patient once again was requested to report any reactions. The patient was then advised regarding appropriate care following acupuncture.

All patients were reassessed for all outcome measures 3 days and then 7 days following the final acupuncture session by the same blinded TMD clinician who had performed the initial assessment. The subjects were also finally asked by the assessor whether or not they knew if they had received the real or sham intervention again through standardised questioning.

#### **Documentation of Interventions**

All treatment interventions, Pain VAS and Functional VAS and other outcome measures were recorded on standardised assessment forms. These were concealed from the assessor to maintain blinding status.

#### **Results**

35 patients were assessed for suitability and of these 27 subjects entered the trial and were randomized into two treatment groups. 7 patients did not meet the inclusion

criteria and were excluded from the study. Only 1 patient dropped out without reason from the real acupuncture group. This occurred after three treatment sessions (see Figure 5 outlining subject flowchart through the study). The following results represent data analysis of 27 subjects who underwent the randomization procedure.

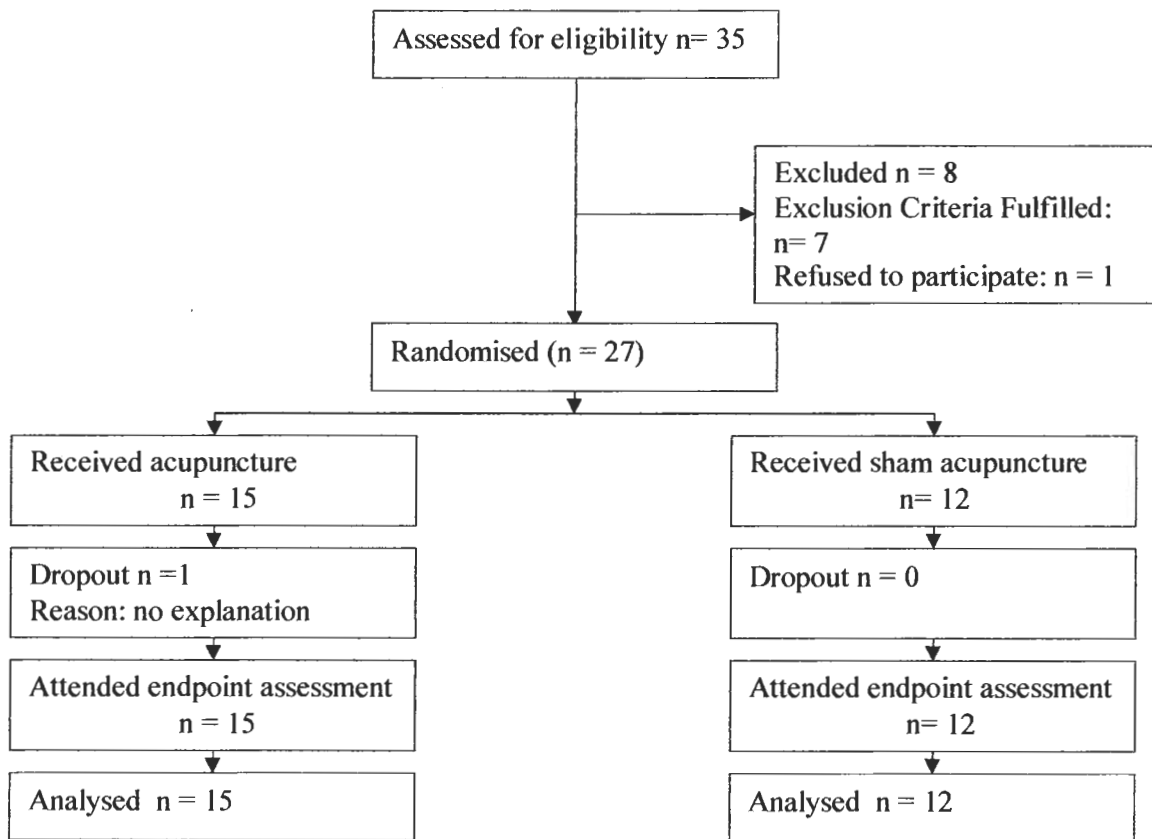


Fig 5

## Patient Characteristics

Table 1 below illustrates the relevant baseline demographics

|                                     | Real Acupuncture    | Sham Acupuncture   | Overall          |
|-------------------------------------|---------------------|--------------------|------------------|
| Sample Size                         | 15                  | 12                 | 27               |
| Age ( $\pm$ SD)                     | 38.3 ( $\pm$ 13.39) | 43.2 ( $\pm$ 4.04) | 40.5 (13.63)     |
| Female: Male sex ratio              | 13:2                | 11:1               | 14:3             |
| Pain Duration (Mean $\pm$ SD) years | 4.0 ( $\pm$ 2.2)    | 4.4 ( $\pm$ 2.8)   | 4.3 ( $\pm$ 2.4) |

Table 1 Patient Characteristics

## Outcome Measures

**Functional Impairment:** Both real and sham groups showed improvement in the mean VAS scores for functional impairment. However, only the real acupuncture treatment group results showed statistical significance (Table 2).

|      | Mean baseline VAS score (cm) | Mean endpoint VAS score (cm) | Mean difference (cm) | Paired T-Test <i>P</i> Value |
|------|------------------------------|------------------------------|----------------------|------------------------------|
| Real | 5.2767                       | 2.3200                       | 2.9567               | 0.003                        |
| Sham | 1.3333                       | 1.2500                       | 0.0833               | 0.339                        |

Table 2 Functional impairment results.

**Pain Intensity:** Similarly, both real and sham groups showed improvement in the mean VAS for pain intensity. However, only the real acupuncture was shown to be statistically significant, whereas the sham acupuncture did not reach a level of significance (Table 3).

|             | Mean baseline VAS score (cm) | Mean endpoint VAS score (cm) | Mean difference (cm) | Paired T-Test P Value |
|-------------|------------------------------|------------------------------|----------------------|-----------------------|
| <b>Real</b> | 6.2133                       | 2.8940                       | 3.3193               | 0.001                 |
| <b>Sham</b> | 1.4167                       | 1.3333                       | 0.0833               | 0.586                 |

Table 3 Pain intensity results.

**Pain Distribution:** for the face chart, the face was divided into three areas: (i) the joint area, (ii) the temporal area and the forehead and (iii) the lower jaw area and the neck (see Fig 3). The numbers of areas affected by pain were found to be significantly reduced in the acupuncture group on the left and right sides at a statistical level. On the sham group, however, a significant improvement was not found (Table 4).

|             | Pain distribution at 2 <sup>nd</sup> visit < pain distribution at baseline | No change | Wilcoxon Signed Ranks Test |
|-------------|--|-----------|----------------------------|
| <b>Real</b> |  |           |                            |
| Left        | 11   | 4         | 0.003                      |
| Right       | 9  | 6         | 0.005                      |
| <b>Sham</b> |  |           |                            |
| Left        | 0  | 12        |                            |
| Right       | 1  | 11        |                            |

Table 4 Pain distribution results

### Inter-incisor Opening and Lateral Movement

**Maximum Opening** In this case, only the real group showed improvement which was statistically significant (Table 5).

|             | Mean baseline opening (mm) | Mean endpoint opening (mm) | Mean difference (mm) | Paired T-Test P value |
|-------------|----------------------------|----------------------------|----------------------|-----------------------|
| <b>Real</b> | 36.0667                    | 39.2667                    | 3.2000               | 0.020                 |
| <b>Sham</b> | 40.7500                    | 39.2500                    | 1.5000               | 0.227                 |

Table 5 Maximum inter-incisor opening

**Maximum Pain Free Opening:** Both treatment groups showed improvement. However, the real acupuncture group reached a statistical level of significance and was much higher than sham group (Table 6).

|             | Mean baseline opening (mm) | Mean endpoint opening (mm) | Mean difference (mm) | Paired T-Test P value |
|-------------|----------------------------|----------------------------|----------------------|-----------------------|
| <b>Real</b> | 28.4667                    | 36.6667                    | 8.2000               | 0.000                 |
| <b>Sham</b> | 36.8333                    | 37.1667                    | 0.333                | 0.674                 |

Table 6 Maximum pain-free opening

**Lateral Movement:** Whilst in the real acupuncture group there was an improvement in lateral movement to the right as well as improvement in the lateral movement to the left, these did not reach statistical level of significance in the lateral movement to the right.

In the sham group, however there was no significant change in either direction (Table 7).

|             | Mean baseline opening (mm) | Mean endpoint opening (mm) | Mean difference (mm) | Paired T-Test P value |       |
|-------------|----------------------------|----------------------------|----------------------|-----------------------|-------|
| <b>Real</b> | <b>L</b>                   | 9.6667                     | 10.8667              | 2.27408               | 0.060 |
|             | <b>R</b>                   | 9.2667                     | 11.8000              | 2.5333                | 0.008 |
| <b>Sham</b> | <b>L</b>                   | 9.2500                     | 9.9167               | 0.6667                | 0.194 |
|             | <b>R</b>                   | 9.5833                     | 9.5833               | 0                     |       |

Table 7 Extent of lateral movement



## Muscle tenderness

Where the presence of muscle tenderness was detected through palpation of the masseter, temporalis and lateral pterygoid muscles, improvements were made much more in the real acupuncture group when compared with the sham group (Table 8).

| Muscle            |             | Improvement in tenderness | No change | Worse | Paired T-Test<br><i>P</i> value |
|-------------------|-------------|---------------------------|-----------|-------|---------------------------------|
| Masseter          | <b>Real</b> |                           |           |       |                                 |
|                   | L           | 9                         | 6         |       | 0.003                           |
|                   | R           | 3                         | 12        |       | 0.083                           |
|                   | <b>Sham</b> |                           |           |       |                                 |
|                   | L           | 0                         | 12        |       |                                 |
|                   | R           | 1                         | 9         | 2     | 0.564                           |
| Temporalis        | <b>Real</b> |                           |           |       |                                 |
|                   | L           | 3                         | 12        |       | 0.083                           |
|                   | R           | 7                         | 8         |       | 0.008                           |
|                   | <b>Sham</b> |                           |           |       |                                 |
|                   | L           | 0                         | 11        | 1     | 0.317                           |
|                   | R           | 0                         | 10        | 2     | 0.157                           |
| Lateral Pterygoid | <b>Real</b> |                           |           |       |                                 |
|                   | L           | 6                         | 9         |       | 0.014                           |
|                   | R           | 6                         | 9         |       | 0.014                           |
|                   | <b>Sham</b> |                           |           |       |                                 |
|                   | L           | 0                         | 12        |       |                                 |
|                   | R           | 1                         | 11        |       | 0.317                           |

Table 8 Tenderness of masticatory muscles

Individual analysis of muscle tenderness statistically significant improvements were found on the left masseter, right temporalis, and on the right and left lateral pterygoid muscles of the group receiving real acupuncture. Within the sham group the majority showed no change from baseline to endpoint.

### TMJ Tenderness

Where joint tenderness was found by examination of both right and left sides lateral and intra-auricular palpation showed greater improvement with real acupuncture subjects compared to the sham group. Overall, the majority of patients showed no change in the TMJ tenderness (Table 9).

| palpation       |             | Improvement in tenderness |   | No change | Worse | Paired T-Test<br><i>P</i> value |
|-----------------|-------------|---------------------------|---|-----------|-------|---------------------------------|
| Lateral         | <b>Real</b> | L                         | 4 | 11        | -     | 0.046                           |
|                 |             | R                         | 6 | 9         | -     | 0.014                           |
|                 | <b>Sham</b> | L                         | 0 | 12        | -     | -                               |
|                 |             | R                         | 1 | 11        | -     | 0.317                           |
| Intra-auricular | <b>Real</b> | L                         | 2 | 13        | -     | 0.157                           |
|                 |             | R                         | 5 | 10        | -     | 0.025                           |
|                 | <b>Sham</b> | L                         | 0 | 12        | -     | -                               |
|                 |             | R                         | 0 | 12        | -     | -                               |

Table 9 Tenderness of TMJs to palpation results.

### Headache

Headache was assessed by asking the patient about it's connection to MP. The presence of headache decreased in the real acupuncture group, compared to no improvement in the sham acupuncture group. The majority of patients, however, showed no change (Table 10)

|      | Improvement in headache | No Change | Worse | Wilcoxon Signed Ranks Test |
|------|-------------------------|-----------|-------|----------------------------|
| Real | 6                       | 9         | -     | 0.014                      |
| Sham | 1                       | 11        | -     | 0.317                      |

Table 10 Presence of headache

### Mouth Deviation

The deviation values did improve slightly for the real acupuncture group, although not significantly. No deviation was found at all within the sham group (Table 12).

|      | Improvement in deviation | No Change | Worse | Wilcoxon Signed Ranks Test |
|------|--------------------------|-----------|-------|----------------------------|
| Real | 6                        | 9         | -     | 0.014                      |
| Sham | 0                        | 0         | -     | -                          |

Table 11 Deviation of mandible on mouth opening

### Joint Sounds

The joint sounds values only improved in one patient for the real acupuncture group. There was no change in the values for the sham group (Table 12).

|             | Improvement in joint sounds | No change | Worse | Wilcoxon Signed Ranks Test |
|-------------|-----------------------------|-----------|-------|----------------------------|
| <b>Real</b> | L                           | 1         | 14    | 0.317                      |
|             | R                           | 1         | 14    | 0.317                      |
| <b>Sham</b> | L                           | 0         | 12    |                            |
|             | R                           | 0         | 12    |                            |

Table 12 TMJ sounds on auscultation

## Park Sham Credibility

None of the subjects believed that they had been treated with the sham needle.

## Discussion

The results demonstrated that real acupuncture had a greater influence on clinical outcome measure of TMJ MP than those of sham acupuncture, and the majority of these reached a level of statistical significance. Therefore, the results support the hypothesis that there is an improvement in signs and symptoms in patients with TMJ MP who receive real acupuncture when compared with a sham acupuncture intervention. Consequently, the null hypothesis can be rejected.

Acupuncture involves the insertion of fine needles at certain points on the body surface known as acupuncture points. Although no unique structures have been found at these sites, there appears to be a relationship between acupuncture points and the presence of high densities of nervous tissue such as large nerve bundles or nerve endings either cutaneous, vascular or muscular.<sup>19,20</sup> An important aspect of acupuncture intervention is point selection as this may involve placement of needles either locally or distally from the target area. However, local segmental points (segment approaches) are generally found to produce a more intense analgesic response.<sup>21, 22</sup> This is said to be not only due to a general widespread analgesic effect but also as a result of direct inhibition at spinal cord level.<sup>19, 20</sup> It has been proposed that using distant acupoints may produce a general body response via mid brain and hypothalamic activation, however the target specificity of distal acupoints has been questioned and their use should be approached with caution.<sup>21, 22</sup> Helkimo<sup>23</sup> demonstrated that acupuncture points often seem to coincide with those

parts of the masticatory muscles exhibiting tenderness on palpation. The same authors showed that (ST 7) corresponded with the location of tender points (latent trigger point) in the masseter muscle of the painful TMJ. It was concluded that the acupuncture point should be in the area of presenting pain or to a nearby peripheral nerve anatomically related to the disorder. This approach may also be help to elucidate possible unknown aetiological and physiological mechanisms involved. In addition, it has been suggested that as few needles as possible should be used in order to discern which needle location is most effective in the management of a condition rather than a multitude of needles of unknown effect.<sup>24</sup>

This study not only gives support to the positive findings of other research into acupuncture and TMJ MP,<sup>13,17,25,26,27,28</sup> but also helps to clarify that the physiological effects of acupuncture are beyond those of placebo. This is in disagreement with several meta-analysis<sup>34,35,36</sup> which suggest that acupuncture has no or limited effects compared to placebo, however the control methods included in these reports differ from the sham acupuncture methodology employed in the study reported here.<sup>37,38</sup> This RCT, therefore provides clinical evidence to support the analgesic effect of acupuncture as well as to the physiological effects, and these may well operate through the endogenous opiate mediated pathways.<sup>19,20</sup>

### **Study Limitations**

It was more difficult to recruit patients than anticipated. Consequently the small sample size led to differences in the mean baseline assessment outcomes between the groups.

Due to time limitations, longer term follow up assessment was not possible. The results, therefore, only apply to the immediate effects of acupuncture. A larger study with an increased follow up period would give more conclusive results and information regarding the long term benefits of acupuncture.

## **Conclusion**

The key findings of this study have been as follows:

- Acupuncture had a positive influence on the signs and symptoms of TMJ MP.
- This study provides evidence that the Park Sham Device was a credible acupuncture control method for trials involving facial acupoints.



## References

1. Gray R, Davies, Quayle A. *clinical guide to temporomandibular disorders*. BDJ Books; 1995.
2. Dworkin SF, LeResche L, DeRouen T, Von Korff M. Research diagnostic criteria for temporomandibular disorders: review, criteria, examinations and specifications, critique. *The Journal of Craniomandibular Disorders*; 1992; **6**:310-355.
3. Jagger R, Bates J, Kopp S. *Temporomandibular Joint Dysfunction. The Essentials*. Oxford: Wright; 1994.
4. Schiffman EL, Fricton JR, Haley D. The relationship of occlusion, parafunctional habits and recent life events to mandibular dysfunction in a non-patient population. *Journal of Oral Rehabilitation* 1992; **19**:201-223.
5. Carlson C, Reid L, Curran S, Studts J, Okeson J, Falace D, Nitz A, Bertrand P. Psychological and physiological parameters of masticatory muscle pain. *Pain* 1998; **76**: 297-307.
6. Huang G, LeResche L, Critchlow C, Martin M, Drangsholt M. Risk factors for diagnostic subgroups of painful temporomandibular disorders (TMD). *Journal of Dental Research* 2002; **81**:284-288.
7. Yap AUJ, Chua EK, Hoe JKE. Clinical TMD, pain-related disability and psychological status of TMD patients. *Journal of Oral Rehabilitation* 2002; **29**:374-380.
8. Fricton JR. Masticatory myofascial pain: an explanatory model integrating clinical, epidemiological and basic science research. *Bulletin du Groupement international pour la recherche scientifique en stomatologie & odontologie* 1999; **41**:14-25.
9. Dahlstrom L, Haraldson T. Bite plates and stabilisation splints in mandibular dysfunction. A clinical and electromyographic comparison. *Acta Odontologica Scandinavica* 1985; **43**:109-114.
10. Dao TTT, Lavigne GJ, Charbonneau A, Feine JS, Lund JP. The efficacy of oral splints in the treatment of myofascial pain of the jaw muscles: a controlled clinical trial. *Pain* 1994; **56**:85-94.
11. Ekberg E, Nilner M, Vallon D. The efficacy of occlusal appliance therapy in patients with temporomandibular disorders of mainly myogenous pain. A randomised controlled trial in a short-term perspective. *Journal of Oral Rehabilitation* 2002; **29**:874.



12. Al-Ani Z, Gray R, Davies S, Sloan P, Glenny A-M. Stabilisation splint therapy for treatment of temporomandibular myofascial pain: A systematic review. *Journal of Dental Education* 2005; **69**: 1242-1250.
13. List T, Helkimo M. Acupuncture in the treatment of patients with chronic facial pain and mandibular dysfunction. *Swedish Dental Journal* 1987; **11**: 83-92.
14. Johansson A, Wenneberg B, Wagersten C, Haraldson T. Acupuncture in treatment of facial muscular pain. *Acta Odontologica Scandinavica* 1991; **49**:153-158.
15. List T, Helkimo M, Anderson S, Carlsson G. Acupuncture and occlusal splint therapy in the treatment of craniomandibular disorders. Part I. A comparative study. *Swedish Dental Journal* 1992; **16**:125-141.
16. Ernst E, White A. Acupuncture as a treatment for temporomandibular joint dysfunction. A systematic review of randomised trials. *Archives of otolaryngology—head & neck surgery* 1999; **125**:269-272.
17. Goddard G, Karibe H, McNeill C, Villafuerte E. Acupuncture and sham acupuncture reduce muscle pain in myofascial pain patients. *Journal of Orofacial Pain* 2002; **16**: 71-76.
18. Rosted P, Jorgensen V. Acupuncture treatment of pain dysfunction syndrome after dental extraction. *Acupuncture in Medicine* 2002; **20**: 193-195.
19. Filshie J, White A. *Medical acupuncture: A western scientific approach*. Churchill Livingstone: Edinburgh; 1997.
20. Stux G, Pomeranz B. *Basics of acupuncture*. 4<sup>th</sup> ed. Springer: Düsseldorf; 1998.
21. Lundeberg T, Hurting T, Lundberg S, Thomas M. Long-term results of acupuncture in chronic head and neck pain. *Pain Clinic* 1988; **2**: 15-31.
22. Kjartansson J, Lundeberg T, Samuelson UE, Dalsgaard CJ. Transcutaneous electrical nerve stimulation (TENS) increases survival of ischemic musculocutaneous flaps. *Acta physiologica Scandinavica* 1988; **134**: 95-99.
23. List T, Helkimo M. Tenderness and acupuncture points in the masseter muscle: A correlation study. *Journal of Orofacial Pain* 1988; **2**: 134-136.
24. Wong J. *A manual of neuro-anatomical acupuncture*. 1<sup>st</sup> ed. The Toronto Pain and Stress Clinic Inc: Toronto, Ontario; 1999.
25. Raustia AM, Pohjola RT, Virtanen KK. Acupuncture compared with stomatognathic treatment for TMJ dysfunction. Part I: A randomized study.

*The Journal of Prosthetic Dentistry* 1985; **54**:581-585.

26. Raustia AM, Pohjola RT, Virtanen KK. Acupuncture compared with stomatognathic treatment for TMJ dysfunction. Part II: Components of the dysfunction index. *The Journal of Prosthetic Dentistry*. 1986(a); **55**:372-376.
27. Raustia AM, Pohjola RT. Acupuncture compared with stomatognathic treatment for TMJ dysfunction. Part III: Effect of treatment on mobility. *The Journal of Prosthetic Dentistry* 1986(b); **56**:616-623.
28. List T, Helkimo M. Acupuncture and occlusal splint therapy in the treatment of craniomandibular disorders. Part II. A 1-year follow up. *Swedish Dental Journal* 1992; **50**: 375-385.
29. Park J, White A, Lee H, Ernst E. Development of a new sham needle. *Acupuncture in medicine* 1999;**17**:110-112.
30. Park J, White A, Stevinson C, Ernst E, James M. Validating a new non-penetrating sham acupuncture device: two randomised controlled trials. *Acupuncture in medicine* 2002; **20**:168-74.
31. Price D, McGrath P, Raffii A, Buckingham B. The validation of visual analogue scales are ratio scale measures for chronic and experimental pain. *Pain* 1983; **17**: 45-56.
32. Walker N, Bohannon R, Cameron D. Discriminant validity of temporomandibular joint range of motion measurement obtained with ruler. *Journal of Orthopaedic and Sports Physical Therapy* 2000; **30**:484-492.
33. Al-Ani Z and Gray R. Evaluation of three devices used for measuring mouth opening. *Dental Update* 2004; **31**: 346-350.
34. Ezzo J, Berman B, Hadhazy VA, Jadad AR, Lao L, Singh BB. Is acupuncture effective for the treatment of chronic pain? A systematic review. *Pain* 2000; **86**:217-25.
35. Mayer D. Acupuncture: an evidence based review of clinical literature. *Annual Review of Medicine*. 2000; **51**: 49-63.
36. Smith LA, Oldman AD, McQuay HJ, Moore RA. Teasing apart quality and validity in systematic reviews: an example from acupuncture trials in chronic neck and back pain. *Pain* 2000; **86**: 119-32.
37. Ryan D. Toward improving the reliability of clinical acupuncture trials: arguments against the validity of “sham acupuncture” as controls. *American*

*Journal of Acupuncture* 1999; **1**:105-109.

38. White A, Filshie J, Cummings T. Clinical trials in acupuncture: consensus recommendations for optimal treatment, sham controls and blinding. *Complementary therapies in medicine* 2001; **9**:237-245.

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## **Legends to illustrations**

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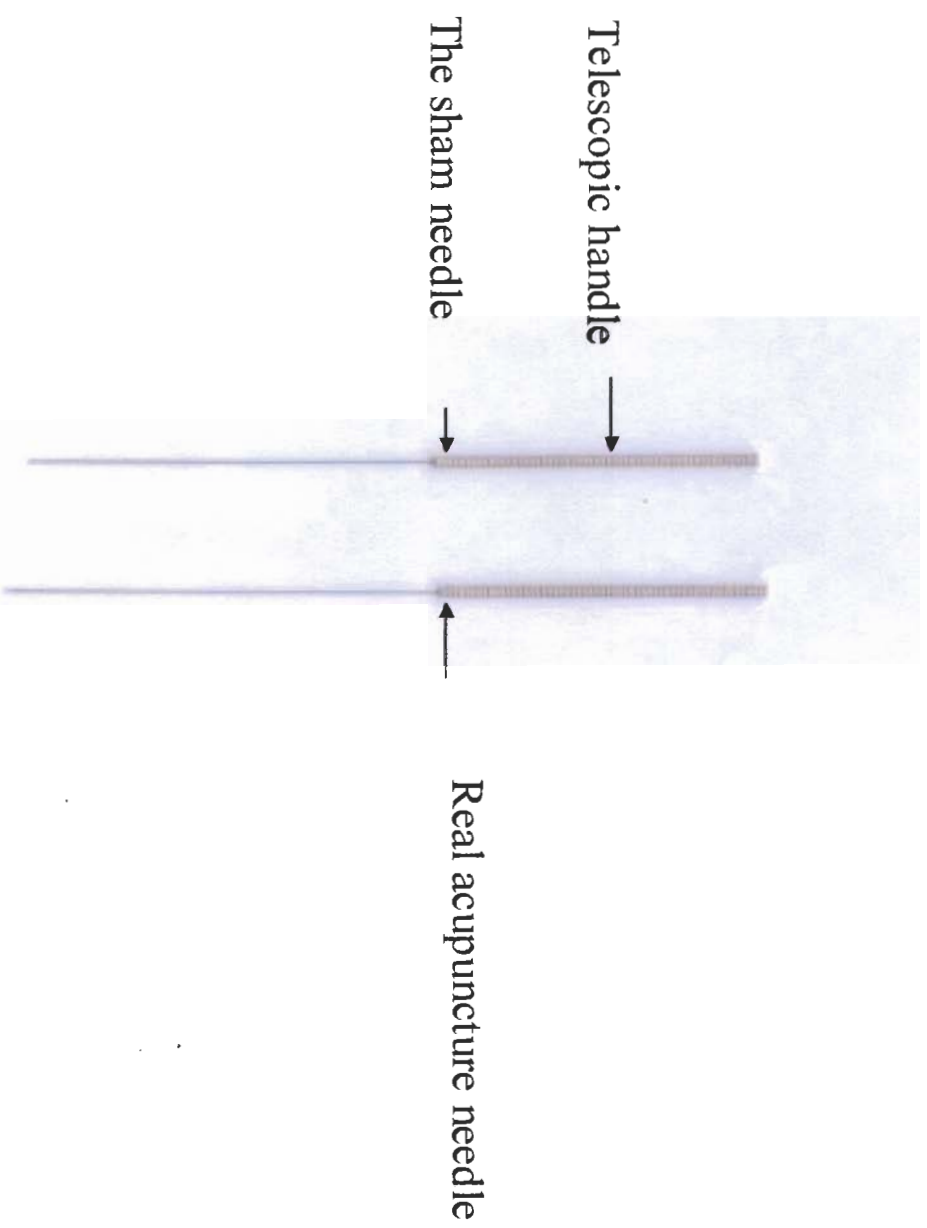


Fig 1. The sham acupuncture needle

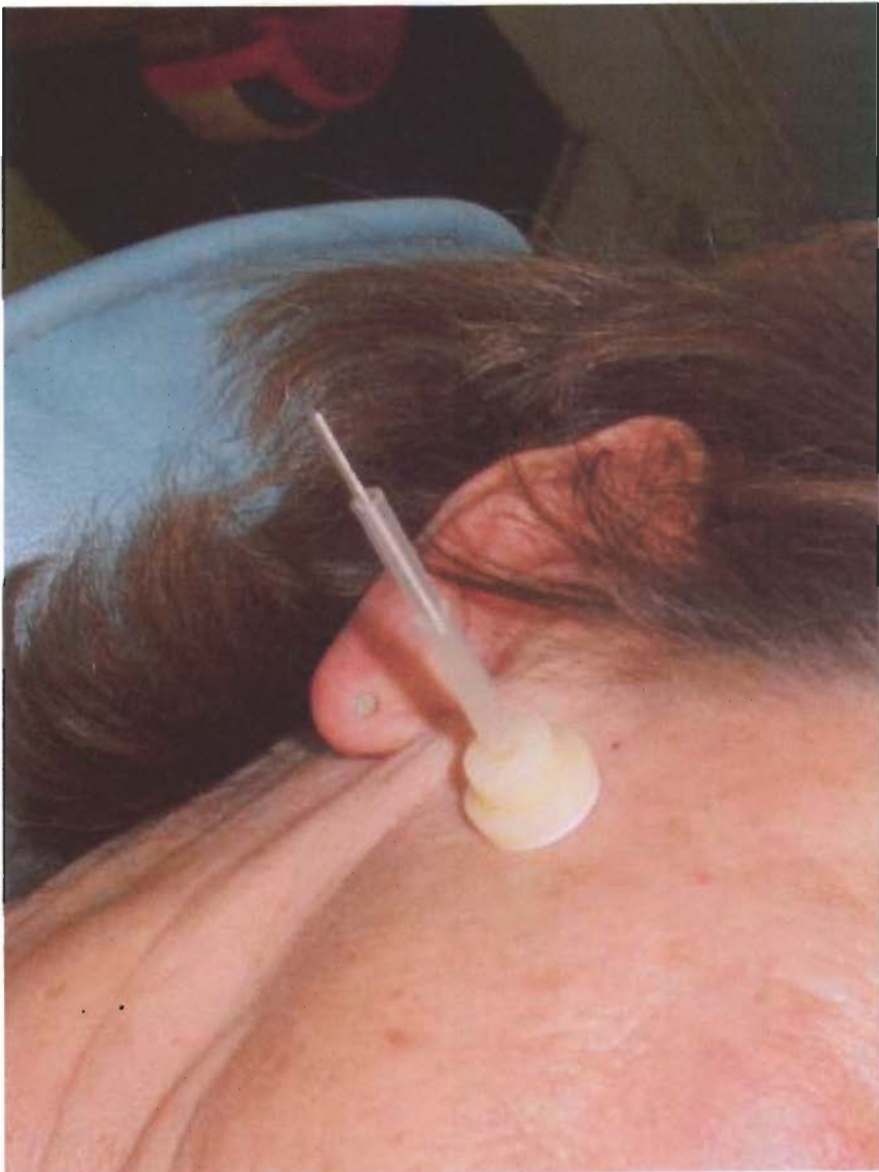



Figure 2: Park Sham Device (PSD) held in place on the skin by a self adhesive pad.

Side of PDS: \_\_\_\_\_ Length of time of complaint: \_\_\_\_\_

Pain Distribution



Number of areas effected: Right \_\_\_\_\_ Left \_\_\_\_\_

Figure 3: The head chart used for recording areas in which the patients reported having experienced pain in relation to the TMD MP.



Figure 4: Acupuncture needles inserted bilaterally at ST 7 acupoint.



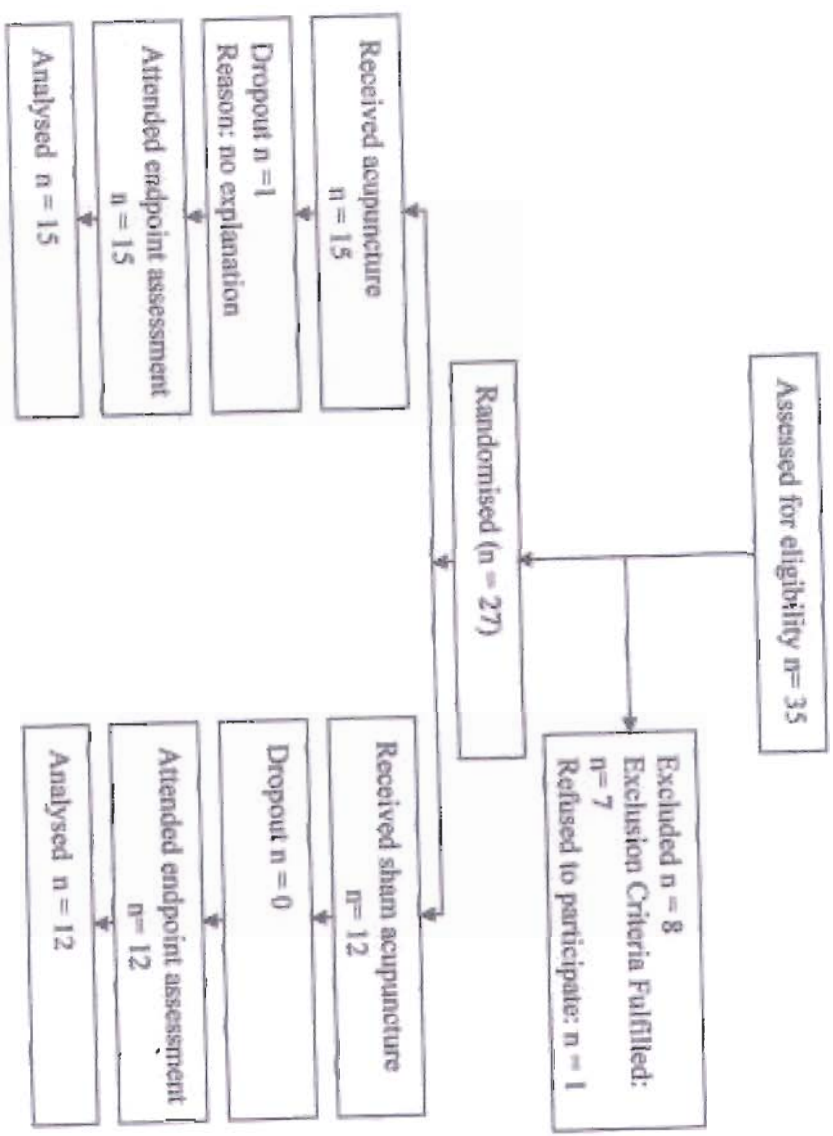


Fig 5. Subject flow chart through the study