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PROTOCOL

Protocol: Testing the Relevance of Acupuncture Theory in the Treatment of Myofascial Pain in the Upper Trapezius Muscle

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Abstract
A protocol for a prospective single-blind parallel four-arm randomized placebo-controlled trial with repeated measures was designed to test the effects of various acupuncture methods compared with sham.

Eighty self-selected participants with myofascial pain in the upper trapezius muscle were randomized into four groups. Group 1 received acupuncture to a myofascial trigger point (MTrP) in the upper trapezius. Group 2 received acupuncture to the MTrP in addition to relevant distal points. Group 3 received acupuncture to the relevant distal points only. Group 4 received a sham treatment to both the MTrP and distal points using a deactivated acupuncture laser device. Treatment was applied four times within 2 weeks with outcomes measured throughout the trial and at 2 weeks and 4 weeks posttreatment. Outcome measurements were a 100-mm visual analog pain scale, SF-36, pressure pain threshold, Neck Disability Index, the Upper Extremity Functional Index, lateral flexion in the neck, McGill Pain Questionnaire, Massachusetts General Hospital Acupuncture Sensation Scale, Working Alliance Inventory (short form), and the Credibility Expectance Questionnaire.

Two-way analysis of variance (ANOVA) with repeated measures were used to assess the differences between groups.

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1. Introduction

Musculoskeletal conditions, including myofascial pain, are among the most common conditions encountered in healthcare clinics across the world [1]. Myofascial pain is a condition characterized by the presence of myofascial trigger points (MTrPs), which are defined as being hyperirritable loci within a taut band of skeletal muscle that are associated with characteristic pain referral patterns [1—5]. Although the precise mechanism for the formation of MTrPs is not completely understood, it appears that the presence of MTrPs in skeletal muscle may attenuate central sensitization within the dorsal horn of the spinal cord [6], and for this reason the treatment of MTrPs may be important. The upper trapezius muscle has been implicated among those muscles that effects neck and shoulder pain [7] and has shown a reasonable degree of interrater reliability for the location and diagnosis of MTrPs [8—12].

Acupuncture-style needling, also known as dry needling, is emerging as a popular treatment method for addressing MTrPs, however, specific methods or protocols have yet to be developed. There is a high degree of variability among the needling methods reported in the literature with regards to needle depth, trigger-point location, duration of effect, needle retention time, number of treatments issued, and even some suggestion that needling distal points may be of equal benefit in the treatment of myofascial pain in the neck and shoulder region.

This study attempted to address some of these issues with outcome measurements taken at multiple time points throughout the study and treatment effect measured at 2 weeks and 4 weeks posttreatment (Table 1).

1.1. Hypothesis

This study was designed to test the following hypotheses: (1) there is no significant difference between needling locally and needling relevant distal points only in the treatment of myofascial pain; (2) needling a combination of both local and distal points is superior to needling either local points or relevant distal points alone in the treatment of myofascial pain; and (3) acupuncture is superior to placebo in the treatment of myofascial pain.

2. Materials and methods

The design of this study was a prospective single-blind parallel four-arm randomized placebo-controlled trial with repeated measures.

Participants ($n = 80$) were randomly allocated to one of four intervention groups. Group 1 (G1) received acupuncture to the painful area (MTrP) identified in the upper trapezius muscle only; Group 2 (G2) received acupuncture to the painful area (MTrP) in the upper trapezius in addition to relevant distal acupoints sites on their extremities; Group 3 (G3) received acupuncture to distal acupoints sites only; and Group 4 (G4) received treatment as per G2, except using a deactivated therapeutic laser device as opposed to an invasive penetrating acupuncture needle. The specific protocols for each group are discussed in detail later.

The outcomes measured during this trial were subjective pain score using a 100-mm visual analog scale (VAS), pressure pain threshold (PPT) using a digital algometer, range of motion (ROM) for cervical lateral flexion using a standard goniometer, and several questionnaires including the Neck Disability Index (NDI), the Upper Extremity Functional Index (UEFI), the Short Form-36 (SF-36), the McGill Pain Questionnaire (MPQ), Massachusetts General Hospital Acupuncture Sensation Scale (MASS), Working Alliance Inventory (WAI), and the Credibility Expectancy Questionnaire (CEQ).

2.1. Recruitment of participants

Participants were self-selecting individuals, able to attend sessions at the University of Technology in Sydney Australia (UTS), experiencing muscle pain, tension or tightness in the region of the upper trapezius muscle. Initial contact was made through a UTS email account for the purpose of distributing information regarding the trial and arranging a session in which the participant was screened against the

Table 1 Outlines of the time points for outcome measurement.

Measure	Pre-S1	Post-S1	Pre-S2	Post-S2	Pre-S3	Post-S3	Pre-S4	Post-S4	2-week post	4-week post
VAS	✓		✓		✓		✓	✓	✓	✓
ROM	✓		✓		✓		✓	✓	✓	✓
PPT	✓		✓		✓		✓	✓	✓	✓
NDI	✓				✓				✓	✓
UEFI	✓				✓			✓	✓	✓
SF-36	✓				✓			✓	✓	✓
MPQ	✓				✓			✓	✓	✓
MASS		✓		✓		✓		✓		
WAI-SF		✓			✓			✓	✓	✓
CEQ	✓				✓			✓	✓	✓

2-week post = follow-up at 2 weeks posttreatment; 4-week post = follow-up at 4 weeks posttreatment; CEQ = Credibility Expectancy Questionnaire; MASS = Massachusetts General Hospital Acupuncture Sensation Scale; MPQ = McGill Pain Questionnaire; NDI = Neck Disability Index; PPT = pressure pain threshold; ROM = range of motion; S1 = first treatment session; S2 = second treatment session; S3 = third treatment session; S4 = fourth treatment session; SF-36 = Short Form-36; UEFI = Upper Extremity Functional Index; VAS = visual analog scale; WAI-SF = Working Alliance Inventory Short Form.

inclusion and exclusion criteria, as well as the diagnostic criteria for inclusion in the study.

The criteria used was an adaptation of those proposed by Lucas et al [12], which have become the standard for assessing pain related to MTrPs. Simons et al [13—15] include electromyography (EMG) measurement of end-plate noise at the neuromuscular synapse, and confirmation via ultrasound among the diagnostic criteria, however, these criteria have been omitted from this study due to low clinical relevance. In practice and research, physical examination and clinical history are used most commonly in the diagnosis of MTrPs [12,16].

The diagnostic criteria selected for this study are as follows:

(1) taut band palpable;
(2) exquisite spot tenderness of a nodule in a taut band;
(3) recognition of complaint by pressure on tender nodule;
(4) painful limit to full stretch range of motion;
(5) pain or altered sensation (in the distribution expected from a trigger point in that muscle) on compression of nodule; and
(6) visual or tactile identification of local twitch response or "jump sign".

In order to qualify for inclusion participants need to display a minimum of three of these criteria in the upper trapezius muscle either bilaterally or unilaterally.

Participants were excluded from the study if they had a history of trauma to the region, cervical radiculopathy, had been diagnosed with fibromyalgia, were unable to communicate in the English language, were younger than 18 (18) years of age, had complex health issues or serious illness, were under the influence of pain modulating medications, were subject to any contraindications for acupuncture therapy, or displayed an unwillingness to participate in the study.

2.2. Location of trial and data collection

The location for all aspects of this trial, including data collection, was the University of Technology, Sydney, Chinese Medicine Clinic.

2.3. Ethical considerations

This study was approved by the UTS Human Research Ethics Committee (HREC 2011000467).

There is currently no standard treatment for myofascial pain, so management of symptoms is often achieved through the use of nonsteroidal antiinflammatory (NSAID) or other analgesic medications. No restrictions were placed on the participants use of these medications, however, they were required to document analgesic medication use.

Acupuncture therapy is a mildly invasive procedure and with that comes some risk of bruising or adverse reactions to treatment. To mitigate this risk all treatment was applied by Australian registered acupuncturists, with no $<$ 7 years clinical experience treating myofascial pain conditions, and any needling of the shoulder region was applied using a muscle lifting technique and an oblique lateral or posterior/anterior needle direction to minimize risk to participants.

2.4. Intervention

Acupuncture needling has an established history of use and demonstrated efficacy in the treatment of myofascial pain, however, there is a high degree of heterogeneity among trials in this area [17]. This study compared local needling, distal needling, and a combination of both against a sham intervention.

Participants in G1 received needling to the local region only according to the concept of trigger point dry needling or *ashi* needling. In this method the upper trapezius was lifted by the hand of the acupuncturist and the needle inserted into the trapezius in an anterior to posterior, or posterior to anterior direction. A lifting and thrusting manipulation was performed five times in the region of the MTrP upon insertion with any local twitch response recorded. Needles were sterile single use 40 mm $\times$ 0.25 mm Chinese-style Vinco acupuncture needles.

Participants in G2 and G3 received needling to distal points relevant to their pain distribution pattern. These points were selected based on the Chinese concept of *liujing* channel pairing, based on their pain distribution pattern, and were needled bilaterally in all cases. The point combinations were either SI 3 (*Huoxi*) and BL60 (*Kunlun*), TE 5 (*Waiguan*) and GB 34 (*Yanglingquan*), or LI 4 (*Hegu*) and ST37 (*Shangjuxu*). These points were selected based on their common indications across multiple popular acupuncture teaching texts [18—20] and their frequency of use in the UTS TCM Outpatient Clinic over 10,000 treatment sessions over 15 years. Needles were inserted in accordance with the depths prescribed in the previously mentioned texts [18—20]. In addition to these distal points, participants in G2 received local needling as per G1.

In G1, G2, and G3 all needles were stimulated at intervals of 5 minutes. The stimulation method used was rotation, to the point of tissue grasp, five times in each direction, or to the tolerance level of the participant. All needle/s were removed after 20 minutes and pressure applied using a gauze swab.

G1 received either one or two needles dependent on whether they exhibited unilateral or bilateral symptoms. G2 received either five or six needles dependent on whether they exhibited unilateral or bilateral symptoms, and G3 participants received four needles per treatment session in all cases.

Participants in G4 received treatment using a deactivated acupuncture laser device. The device makes sound and to all purposes looks like it is delivering infrared laser light to the trigger point sites on the trapezius muscle, as well as the relevant distal points. During each session the participant received two rounds of this treatment to each point for 45 seconds each, with a break of 2 minutes between rounds. These participants served as the control group.

No specific sensation was sought by the treating practitioner in the performance of the needling, however, any sensations felt by the participant were recorded using the MASS instrument.

All groups received four treatment sessions within 14 days as per their group allocation.

2.5. Control group

Within the acupuncture literature there is a history of sham interventions that are reasonably criticized for being active in nature rather than truly inert shams [21]. Examples of such shams include shallow needling, non-acupuncture point needling [22] or noninsertion needle devices [23,24]. These methods, in particular the use of nonacupuncture points or shallow insertion, have been contentious over the years [25]. Many of these methods have been shown to be therapeutic and are actually incorporated into the therapeutic techniques of various acupuncture traditions [26].

The use of the deactivated laser circumvents these issues by providing a credible sham method of acupuncture that is also biologically inert for all intents and purposes.

Laser has shown some effectiveness in the treatment of MTrPs [27], which further strengthens the credibility of the sham.

The Working Alliance Inventory (WAI) and Credibility Expectancy Questionnaire (CEQ) were used to assess the validity of the sham compared with the interventions, which is discussed later.

2.6. Adverse events and discontinuation from study

Adverse events and discontinuations from study were recorded and reported in any published literature resulting from this trial. Data were analyzed on the basis of intention to treat.

2.7. Outcome measures

Among the literature on acupuncture/dry needling in the treatment of myofascial pain in the neck and shoulder region the most common outcomes measured are subjective pain using VAS, range of motion in lateral flexion of the neck, and pressure pain threshold using algometry. This study utilized these common outcome measures in addition to a variety of other tools to measure more global effects, these measures are the Neck Disability Index (NDI), the Upper Extremity Functional Index (UEFI), the Short Form-36 (SF-36), the McGill Pain Questionnaire (MPQ), and Massachusetts General Hospital Acupuncture Sensation Scale (MASS). In addition to these measures this trial also utilized a Working Alliance Inventory Short Form (WAI-SF) and the Credibility Expectancy Questionnaire (CEQ) to assess aspects of the therapeutic relationship and placebo effect.

2.8. Pressure pain threshold

Pressure pain threshold (PPT) using an algometer is commonly used in studies of myofascial pain to measure sensitivity of the local region to pain. The algometer has been shown to be a reliable measure [28—33].

2.9. Visual analog pain scale (VAS)

The participants' subjective feelings of pain was measured using a VAS, which consisted of a 100-mm line, with one end representing "no pain at all" and the other end indicating "worst pain imaginable". Participants were asked to mark along this line the point that best represents their current painful symptoms.

The VAS is a commonly used measure in similar studies [34—54] and has been assessed as having a moderate to good level of reliability [55] particularly when assessing severe pain [56].

The validity of the VAS has been criticized [55,57] as it is subject to bias, particularly with repeated measures, however, in this trial this bias was offset somewhat by the use of a range of other pain measures such as the PPT, MPQ, NDI, UEFI, and SF-36. The use of other measures has been shown to increase the reliability of the VAS [57]. Although the VAS has certain issues regarding validity and bias, the subjective sensation of pain for the participant is an important clinically applicable measure.

2.10. Range of motion (ROM)—cervical lateral flexion

One of the key diagnostic signs for MTrPs is painful restriction of movement. ROM was measured for cervical lateral flexion using a goniometer with the pivot placed at the spinous process of the seventh cervical vertebra.

ROM has been used in many studies for myofascial pain in the upper trapezius muscle and it has been observed that changes between 5° and 10° are necessary to be considered significant [58].

2.11. Neck Disability Index (NDI)

The upper trapezius muscle exerts influence over the shoulder and cervical regions, for this reason the NDI and UEFI-20 were selected to assess both cervical and upper extremity function. The NDI is a one of the most common instruments for assessing self-rated disability in people exhibiting painful neck symptoms [59,60] and consists of a 10-item scale where each item is rated on a 6-point scale from 0 to 5 with 0 indicating no disability and 5 representing full disability.

The reliability of the NDI has been supported by a systematic review, which reported the minimum detectable change (MDC) in uncomplicated neck pain to be 5/50 and found the NDI strongly correlated to similar indices ($>$0.70) [61].

2.12. Upper Extremity Functional Index 20 (UEFI-20)

The UEFI-20 is a 20-item measure of function of the upper limb and is used to measure functional changes over time.

The reliability of the UEFI-20 has been reported as being 0.94 with the minimum detectable change values being 9.4/80 [62].

2.13. Short Form 36 Health Survey (SF-36)

The SF-36 is a commonly used quality of life measurement tool. The reason for inclusion of the SF-36 in this study was to assess the quality of life of the participant, as an indication of general health throughout the course of the study.

The SF-36 measures eight areas of health, those being: (1) physical functioning; (2) role-physical; (3) bodily pain; (4) general health; (5) vitality; (6) social functioning; (7) role-emotional; and (8) mental health.

Reliability statistics for each of these areas have been measured as being $>$ 0.80 in $>$ 25 studies, with physical and mental summary scores usually exceeding 0.90 [63].

As all intervention groups received a form of acupuncture therapy, the SF-36 will provide valuable information regarding the global or nonspecific effects of each of these interventions. According to traditional acupuncture theory, those individuals receiving relevant distal points may show systemic health effects beyond those expected from treating the painful region only.

2.14. McGill Pain Questionnaire (MPQ)

The MPQ has been commonly used since 1975 as an outcome measure to assess qualitative and quantitative aspects of pain [64]. This instrument allocates a score, based on the selection of words to describe the person's pain, which have numerical values attached to them, known as a pain rating index (PRI). This instrument also allocates a score based on the number of words chosen (NWC) by the patient to describe their pain, and a five point numerical pain intensity scale known as the present pain index (PPI).

The internal consistency of the PRI, NWC, and PPI has been reported as being 0.89—0.90 and the test—retest reliability of this instrument has been reported as being 70.3% [65].

The MPQ was used in this study to measure the participant's change in pain over time and strengthen the validity of other pain measures such as the VAS.

2.15. Working Alliance Inventory Short Form (WAI-SF)

The WAI-SF was used in this study to assess whether there is a correlation between the perceived therapeutic relationship and the effect of treatment. The WAI-SF consists of 12 questions, regarding the therapeutic relationship, which were answered using a seven point scale, from never (1) to always (7).

According to Bandalos et al [66] (2008) the WAI-SF is a reliable measure of therapeutic relationship and studies have shown that mean reliability estimates for WAI-SF scores range from 0.79 to 0.97, with a modal estimate of 0.92.

2.16. Credibility Expectancy Questionnaire

This was used to measure the participant expectation of the treatment they received and the perceived credibility of the treatment they received. The Credibility Expectancy Questionnaire (CEQ) was used to assess differences between the control group and the treatment groups with regards to these measures.

This instrument measures both expectancy and credibility and demonstrates high internal consistency for both measures (0.79—0.90 for expectancy and 0.81—0.86 for credibility) [67]. The test—retest reliability was found to be 0.82 for expectancy and 0.75 for credibility [67].

2.17. Massachusetts General Hospital Acupuncture Sensation Scale (MASS)

The MASS was used to obtain information regarding the sensation the patients' experience during the treatment session. Results of this measure will inform future protocols and guidelines regarding the prognostic value of sensation during treatment.

2.18. Sample size, randomization, and blinding

Participants were recruited and randomly allocated to four groups of equal size ($n = 20$) using computer generated permuted block randomization.

Group allocation remained concealed to the outcome assessor with the person administering the interventions contacting the person with the allocation list remote to the trial site. The treating practitioner remained blind to the outcome measurements.

2.19. Data management and statistical analysis

Data was collected in paper form and was stored in a secure cabinet at UTS. Data collected was tabulated in a digital format in a deidentified form and kept under password protection.

Two-way analysis of variance (ANOVA) with repeated measures was the statistical method used to assess the differences between groups for the various outcome measures.

2.20. Timeline

Upon acceptance into the trial participants underwent a 2 week intervention period followed by two outcome measures sessions at 2 weeks and 4 weeks posttreatment. The total time of involvement in this trial for participants was 6 weeks from the first session.

3. Discussion

There are numerous trials assessing the value of acupuncture/dry needling applied to the local region of the upper trapezius muscle in the treatment of myofascial pain. Similarly there are a number of studies assessing the utility of distal needling and the effects on the upper trapezius muscle. Among the studies of various acupuncture methods in the treatment of myofascial pain in the upper trapezius muscle there have been comparisons with physiotherapy [68—73], lidocaine injections [74—78], corticosteroid injection [79], botulinum toxin A (Botox) [77], and laser [80—82], but none have assessed various acupuncture approaches. This trial attempted to fill a gap in the literature comparing local needling with distal needling and a

Table 2 Checklist for items in Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) 2010.

Item	Detail	Page No.
1. Acupuncture rationale (explanations and examples)	(1a) Style of acupuncture (e.g., traditional Chinese medicine, Japanese, Korean, Western medical, five element, ear acupuncture, etc)	4
	(1b) Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate	4
	(1c) Extent to which treatment was varied	4
2. Details of needling (explanations and examples)	(2a) Number of needle insertions per individual per session (mean and range where relevant)	4
	(2b) Names (or location if no standard name) of points used (uni/bilateral)	4
	(2c) Depth of insertion, based on a specified unit of measurement, or on a particular tissue level	4
	(2d) Response sought (e.g., *de qi* or muscle twitch response)	4
	(2e) Needle stimulation (e.g., manual, electrical)	4
	(2f) Needle retention time	4
	(2g) Needle type (diameter, length, and manufacturer or material)	4
3. Treatment regimen (explanations and examples)	(3a) Number of treatment sessions	5
	(3b) Frequency and duration of treatment sessions	4, 5
4. Other components of treatment (explanations and examples)	(4a) Details of other interventions administered to the acupuncture group (e.g., moxibustion, cupping, herbs, exercises, lifestyle advice)	N/A
	(4b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients	3
5. Practitioner background (explanations and examples)	(5) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience)	3
6. Control or comparator interventions (explanations and examples)	(6a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice	5
	(6b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above.	4, 5

combination of the two to give some indication of the most efficacious approach.

The trial was designed to accord with the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) requirements (see Table 2). This is important in reporting the study and allowing study reviewers sufficient information concerning the acupuncture intervention. This is important as the trial incorporates two styles of acupuncture, that of trigger point therapy and classical Chinese acupuncture.

Other implications for this trial included the comparison of local and distal needling approaches. If distal needling is shown to have similar clinical efficacy as local needling then this may have positive benefits with respect to patient safety in the future.

Disclosure statement

The authors declare that they have no conflicts of interest or financial interests related to the material in this manuscript to declare.

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