Developing and validating a sham acupuncture needle

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ABSTRACT
Objectives: To develop a sham needle device and test its credibility as a control for acupuncture when used in a randomised controlled trial of myofascial trigger point needling in patients with whiplash associated pain.

Methods: Sham needles were developed by blunting true acupuncture needles. Whiplash injured patients (<16 weeks duration) were randomly allocated to receive either true acupuncture or the "placebo" sham needle control. The true and sham needling interventions were delivered using the same standardised procedure. Patients were informed that they would receive either real or placebo needles, and asked (i) to state which treatment they believed they had received (treatment belief); (ii) to complete the four item Borkovec and Nau self-assessment credibility scale. Results were compared between groups and the analysis explored whether a patient’s previous experience of acupuncture was related to their treatment belief. Other outcomes of the study will be reported elsewhere.

Results: 20 patients received the true acupuncture and 21 received the sham. There was no significant difference between the treatment beliefs of the two groups ($\chi^2 = 1.51, p>0.2$) nor in the mean item scores on the Borkovec and Nau credibility scale (t test, p values ranged from 0.38 to 0.87). Of the patients in the sham acupuncture group who had previous experience of acupuncture, none recorded receiving the sham intervention.

Conclusion: Within the context of this pilot study, the sham acupuncture intervention was found to be a credible control for acupuncture. This supports its use in a planned, definitive, randomised controlled trial on a similar whiplash injured population.

In a clinical trial, a placebo intervention controls for the “non-specific” treatment effects that are directly associated with a test intervention. Such non-specific (psychophysiological) effects can be produced by, for example, a patient’s desire for symptom relief, an expectation that the given treatment will ease symptoms or a learned conditioning response based on previous experience.1–3 Placebo controls also reduce or eliminate the effects of bias in the patient’s assessment of the effect of treatment.

The choice of placebo control intervention for acupuncture is problematic. An effective and credible placebo in an acupuncture trial should mimic all aspects of the true “active” treatment, while being physiologically inert.4 Interventions used as placebo controls for acupuncture in clinical trials include both non-needleing and needling procedures. Non-needling interventions include sham transcutaneous nerve stimulation (TENS) and sham laser, which are set up in the usual way but inactivated.5,6 Whilst such interventions are likely to be physiologically inert, the “treatment experience” may differ from that of needling, and therefore these interventions may not control for all the non-specific effects of acupuncture. Needling interventions include needling non-acupuncture points or irrelevant points (ie, away from the region of pain),7 or needling superficially (ie, subcutaneously).8 Whilst these interventions most likely mimic the true acupuncture experience, it is unlikely that they are physiologically inert.9 In view of the uncertainty on whether these control devices are truly inactive, they are most accurately described as “sham” acupuncture. The current evidence suggests that the least active and most credible placebo control for true acupuncture is a non-penetrating acupuncture needle.10,11

Non-penetrating needles which have previously been developed and validated as a control for acupuncture, incorporate a small holding device which keeps the needle in place.10,12 These needles provide an adequate control for acupuncture where the needles remain in situ for a period of time. However, we required a control for an acupuncture intervention in which a needle is manipulated up and down within a muscle (for only a few seconds), before being removed. Therefore, as part of our study—a pilot randomised controlled trial (RCT) of myofascial trigger point (MTrP) acupuncture needling for whiplash associated pain—we developed a sham needle intervention to mimic this specific needling technique and evaluated its adequacy as a placebo control.

This report concerns only the development of the sham device; the main results of the pilot RCT will be reported elsewhere.

The study, which conformed with principles outlined in the Declaration of Helsinki, was approved by the Cornwall and Plymouth Research Ethics Committee (REC reference: 07/Q2103/3) and Plymouth Hospitals NHS Trust Research and Development sub-committee.

METHOD
Developing the sham needle
Sham needles were developed by blunting true acupuncture needles (Seirin B-Type 0.35 mm x 50 mm). Initial attempts to remove the needle point with wire-cutters produced a blunted needle with an uneven burred edge. The needle felt sharp when applied to the skin, and was clearly potentially traumatic and therefore unsatisfactory. The University of Plymouth, Faculty of Technology, was approached for advice and after some trial and error a method for accurately producing a blunt non-penetrating needle was developed. Specialist cutting equipment was used to remove the needle point and a spring-loaded device was engineered to hold the needle so that it could be polished flat using a diamond honing stone (Eze-Lap superfine, Eze-Lap diamond honing stone (Eze-Lap superfine, Eze-Lap...
Removing the needles from their packaging and handling them during the blunting process meant that they were no longer sterile. Therefore, to ensure that the blunted needles did not pierce the skin during the clinical trial (and for patient comfort) each needle was cut and polished individually and checked for sharpness against the investigator’s finger tip. As a precaution against infection, each patient was treated with a separate sham needle.

Recruitment and information
The principal investigator (ET) approached patients referred to Derriford Hospital physiotherapy department (during May to December 2007) with a recent whiplash injury (<16 weeks duration). Patients were contacted by telephone, offered a physiotherapy appointment and informed that they would receive (in the post) an information leaflet inviting them to participate in a research project. The information leaflet contained the statement: “You will receive treatment with either acupuncture needles or placebo needles”.13

Patients eligible to take part were those referred with a whiplash injury of two to 16 weeks duration who fulfilled the Grade II Quebec Task Force classification of whiplash associated disorders (WAD), were aged 18 or over and were able to give fully informed consent. Patients excluded were those with clinical signs and symptoms of upper cervical instability or neurological deficit, a history of serious co-morbidity, contra-indications to acupuncture, or were receiving or had received treatment (other than medication), for example, private physiotherapy or osteopathy.

Assessment and enrolment
On their first appointment, all patients underwent a routine physiotherapy assessment and received a programme of standardised physiotherapy care devised in line with current clinical guidelines for the physiotherapy management of WAD.14 On the second appointment, patients who were willing and eligible to take part were enrolled into the study.

ET, an experienced musculoskeletal physiotherapist with 17 years clinical experience, examined muscles of each patient for clinically identifiable MTrPs in any muscles which corresponded to the patient’s region of pain (after Simons et al15 predicted patterns of pain for MTrPs). MTrPs were defined as “tender muscle points (which occur with or without a taut band) and which on sustained palpation (up to 10 seconds) reproduced the patient’s pain”. Following the physical examination patients...
were randomised to receive either “true acupuncture” or “placebo acupuncture”. The random allocation sequence was computer-generated using block size of four, held by the pharmacy department at the research site and concealed from the investigator.

**Interventions**

To minimise the difference between the psychological impact of the two interventions and the (unblinded) investigator’s approach, both interventions were delivered using the standardised procedure. The patient was shown a true acupuncture needle and given the following explanation:

I’ll first mark on your skin where the tender points are which relate to your pain. I’ll then treat each point one at a time. You’ll feel the needle being tapped against your skin using the guide tube. I’ll then move the needle up and down five or six times depending on what you are feeling [visual demonstration using the needle and mimicking the needling technique]. While I am doing this let me know if you feel anything anywhere else. After I have treated each point I’ll ask you whether or not you are happy to continue or if you want to stop. Is that okay?

The needles were prepared out of sight of the patient, and patients were positioned lying in such a way that they were unable to see the treatment. For genuine needling, a Seirin 0.25 mm diameter (30 or 40 mm length) needle was unwrapped and inserted into the site of a MTrP using a guide tube. The muscle was pinched and held away from underlying structures. The needle was then moved up and down within the muscle in a “sparrow pecking” motion (average six to seven repetitions depending on the patient’s response). The needle was discarded into a sharps container and the empty needle packaging collected in a tray next to the sharps container. A new needle was used to treat each MTrP.

For sham needling, the pre-prepared sham needle was tapped against the patient’s skin using a guide tube, which was then removed while holding the needle with the fingers. The muscle was pinched and held away as before, while the needle was gently pressed up and down against the skin in a sparrow pecking motion (average six to seven repetitions depending on the patient’s response). The needle was then placed in a tray, but a true acupuncture needle was discarded into the sharps container and the empty packaging collected, with the intention of mimicking the genuine acupuncture procedure. To treat each additional point, a new acupuncture needle was unwrapped, placed in the tray and discarded after the intervention, but the same sham needle was used for the intervention. In both groups, patients received one treatment per week, and between two and six treatments.

**Evaluation of credibility**

During the first appointment patients were asked if they had had acupuncture before. This information was used to explore if a patient’s previous experience of acupuncture predicted a correct statement of receiving the sham intervention.

On the third appointment, patients were presented with a written evaluation form. This asked “Which treatment do you believe you received?” and offered the replies “traditional acupuncture”, “placebo acupuncture” or “uncertain”. This response is referred to here as “treatment belief”.

At the same appointment, the Borkovec and Nau self-assessment scale was used to assess the patient’s confidence in the treatment they had received.16 17 The four item scale asks:

- **How confident would you be in recommending this treatment to a friend who suffers from the same complaint?**
- **How successful do you think this treatment would be in alleviating other complaints?**
- **How logical does this treatment seem to you?**

Each item was scored independently using an unmarked 6 cm line (visual analogue scale), labelled on the left by “not at all confident/logical” and on the right by “extremely confident/logical”. Scores were summed to provide a total credibility score (24 representing complete confidence/credibility).

To investigate whether there was a difference between true and sham acupuncture in the physical sensation experienced by patients, each patient was asked (immediately following the first treatment): “Using your own words how would you describe the sensation you felt when the needles were in place?” If the patient found this difficult they were asked to select a word or words from a list of pain descriptors taken from the McGill pain questionnaire.18

Additionally, at the start of each treatment session, patients were asked to report any adverse reaction they had experienced to the previous treatment in order to evaluate whether treatment beliefs are driven by the occurrence of adverse events.

**Data analysis**

For treatment belief, between group comparisons were presented as frequency and proportions and analysed using Pearson’s $\chi^2$ test.

Means and 95% confidence intervals (CIs) were calculated for the four individual items scored on the Borkovec and Nau scale. Independent t tests were used to compare groups. Descriptive data and proportions were presented to compare (i) the needle sensation and (ii) the range and frequency of adverse reactions experienced by patients receiving true acupuncture with those receiving sham acupuncture. Statistical analyses were carried out using SPSS V.15 software.

**RESULTS**

Ninety-two patients were approached, of which eight failed to attend their initial assessment. Twenty-five (30%) of the 84 patients assessed for recruitment were ineligible. Of 59 eligible patients, 18 (21%) declined to take part. Forty-one patients (70% of those eligible) were recruited into the trial, 20 allocated to receive true acupuncture and 21 allocated to receive the sham acupuncture. One patient in the acupuncture group and three in the sham acupuncture group dropped out without explanation before all credibility data had been collected (table 1).

About 20% more of the patients in the sham acupuncture group believed they received true acupuncture than in the true acupuncture group (table 1), but this difference was not statistically significant. Furthermore, no statistically significant between group difference was recorded in the mean scores on the Borkovec and Nau scale. However, the lack of significant difference is not equal to the proof of equivalence due to the small sample size.

Of the seven patients in the sham acupuncture group who had received acupuncture previously, six stated that they believed they had received true acupuncture while the seventh dropped out before credibility data could be collected. Of the two patients in the acupuncture group who had received acupuncture previously, one believed they had received true acupuncture and one was uncertain. Only one patient in the sham acupuncture group stated that they believed they had received the placebo intervention. However, this patient also recorded the highest total credibility score of 23.4 out of 24.0 on the Borkovec and Nau scale, which appears somewhat contradictory.
In respect of the most commonly reported adverse reactions, 16/20 (80%) of patients who received true acupuncture reported a temporary increase in pain post treatment compared with 9/20 (43%) in the sham acupuncture group ($\chi^2 = 5.23, \text{df }= 1, p = 0.05$). In the majority of cases the increase in pain lasted no longer than the day of treatment. Nausea or tiredness was experienced by a small number of patients in both groups (7/20 (35%) of the acupuncture group; 6/21 (28%) of the sham acupuncture group). No patient ceased treatment because of adverse events.

The most commonly reported descriptors used to describe the sensation of needling are shown in fig 3. The most notable apparent difference between the two groups was a higher proportion reporting aching and heavy sensations associated with true acupuncture needling (n = 15) compared with the sham acupuncture needling (n = 5).

**DISCUSSION**

**Summary of findings**

Within the context of this pilot RCT, the credibility of the sham acupuncture intervention was found to be no different from that of the genuine acupuncture treatment. The incidence of reported adverse reactions, and the physical sensations experienced by patients in the two intervention groups appeared to differ, but these apparent differences did not seem to undermine the credibility of the sham intervention. This study’s findings support the appropriateness of this sham acupuncture device in a definitive trial on a similar whiplash injured population. Two forms of blinding index have been proposed for further statistical analysis of responses to blinding questions, but we do not consider that their interpretation is yet sufficiently well developed to add to our findings.19

**Strengths**

Recent research has shown that the therapist/patient relationship is a potent component of the placebo effect of acupuncture,20 thus suggesting that the context or delivery of the sham acupuncture device is important, not just the selection of the device itself. To strengthen the reliability of any evaluation of the specific effects of acupuncture, a test intervention and placebo control should therefore be delivered in the same way. A strength of this study was the standardisation of the interaction and all procedures used when delivering interventions, and which aimed to produce an equivalent therapeutic experience for all patients irrespective of treatment allocation.

**Limitations**

The main limitation of this study is the small number of subjects involved in this pilot study. Fundamentally, we were trying to evaluate the equivalence of the two procedures, not their difference. The comparative statistical tests we used in this situation carry the risk of a type II error—not identifying a true difference—which in turn risks producing a false negative result. In the responses to all four credibility questions, there were small trends in the direction of lower credibility of the sham intervention. However, there was also a trend towards greater treatment belief in acupuncture in the sham group. It was interesting to note that “sharpness” was reported similarly in the two groups and seems likely to be one major factor in the sham intervention’s credibility. Overall therefore, we have confidence that the sham device will not result in loss of blinding. Nonetheless, this sham needle can only be used out of the patients’ line of vision and when the needle does not need to be left in situ, both of which applied to this study.

If a definitive study of acupuncture and sham acupuncture is planned, it may be necessary to involve several centres and

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**Table 1** The number and proportion of patient’s belief of intervention received, and the mean credibility scores for the two interventions

<table>
<thead>
<tr>
<th>Test of credibility</th>
<th>Acupuncture group (n = 19)</th>
<th>Sham acupuncture group (n = 18)</th>
<th>$\chi^2$ Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous acupuncture</td>
<td>2 (10)</td>
<td>6 (33)</td>
<td></td>
</tr>
<tr>
<td>Treatment belief</td>
<td>10 (53)</td>
<td>13 (72)</td>
<td>$\chi^2 = 1.51; *\text{df }= 1, p &gt;0.2$</td>
</tr>
<tr>
<td>1. Acupuncture</td>
<td>4.3 (4.0 to 4.6)</td>
<td>4.0 (3.4 to 4.7)</td>
<td>0.38</td>
</tr>
<tr>
<td>2. Placebo</td>
<td>4.3 (3.6 to 5.0)</td>
<td>4.2 (3.6 to 4.8)</td>
<td>0.84</td>
</tr>
<tr>
<td>3. Uncertain</td>
<td>4.8 (4.4 to 5.3)</td>
<td>4.5 (3.9 to 5.2)</td>
<td>0.43</td>
</tr>
<tr>
<td>Borkovec and Nau credibility scale (maximum score)</td>
<td>Mean (95% CI)</td>
<td>Mean (95% CI)</td>
<td>$p$ Value</td>
</tr>
<tr>
<td>“Confident” (6)</td>
<td>4.3 (4.0 to 4.6)</td>
<td>4.0 (3.4 to 4.7)</td>
<td>0.38</td>
</tr>
<tr>
<td>“Logical” (6)</td>
<td>4.3 (3.6 to 5.0)</td>
<td>4.2 (3.6 to 4.8)</td>
<td>0.84</td>
</tr>
<tr>
<td>“Recommend” (6)</td>
<td>4.8 (4.4 to 5.3)</td>
<td>4.5 (3.9 to 5.2)</td>
<td>0.43</td>
</tr>
<tr>
<td>“Successful” (6)</td>
<td>4.1 (3.5 to 4.7)</td>
<td>4.0 (3.3 to 4.7)</td>
<td>0.87</td>
</tr>
</tbody>
</table>

*df = 1 as “placebo cells” combined with “uncertain cells”; t-test.
Summary points

- We needed a sham device for use in a trial of acupuncture for whiplash injury.
- A sham, non-penetrating needle was prepared with special equipment, and used in a pilot study with standardised interaction and procedures.
- The credibility of the sham acupuncture intervention was no different from that of the acupuncture treatment.
- This sham needle is appropriate for use out of the patient’s line of vision and when the needle does not need to be left in situ.

Applicability

The main advantages this needle has over other sham needle devices, such as the Streitberger and Park needle, are that it costs little and is simple to use. The main disadvantage is its limited application.

Some patients who received the sham acupuncture intervention experienced a physical needle sensation and reported adverse responses to treatment. This may be confirmation that the sham needle intervention was not physiologically inert. Alternatively, these responses could be psychologically generated in relation to the patient’s expectations based either on a previous experience of acupuncture or on the information given to the patient prior to their consenting into the study. In the additional, the physical sensation the patient experiences on needling, be it with true or sham acupuncture needles, may predict treatment response. For example, clinical research has shown that the heavy, aching de qi sensation elicited on deep acupuncture needling produces a greater and more prolonged acupuncture analgesia than the minimal sensation elicited by needling superficially. Therefore, in this study it could be hypothesised that the patients who experienced a heavy/aching sensation (15/20 in the true acupuncture group; 3/21 patients in the sham acupuncture group) would respond best to treatment (irrespective of the intervention given). Indeed, a previous study comparing genuine acupuncture with a superficial needling control in patients with osteoarthritic knee pain, found that patients in both groups who experienced a de qi needle sensation demonstrated a better response to treatment. Analysing the effect that a physical sensation, which is common to both intervention groups (eg, in this study, a sharp/pricking sensation), has on a patient’s response to treatment, may also help our understanding of what constitutes an “active” or an “inert” intervention.

CONCLUSION

Within the context of this pilot study, the sham acupuncture intervention was credible as an acupuncture control. This supports its use in a definitive RCT on a similar whiplash injured population.
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