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Experiences of Acupuncturists in a Placebo-Controlled, Randomized Clinical Trial

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ABSTRACT

Background: This paper describes the experiences of 8 licensed acupuncturists in a placebo-controlled randomized clinical trial (RCT). This information is important to the design and conduct of high-quality trials.

Methods: We conducted a RCT (N = 135) with a 2-week placebo run-in followed by 4 weeks of twice-weekly treatments comparing genuine to sham acupuncture (using the Streitberger placebo needle) in the treatment of arm pain caused by repetitive use. At the end of this study, we conducted written structured interviews with 8 participating acupuncturists. The acupuncturists were not aware of the study's results at the time of these interviews. The questions focused on their experiences in the study, adherence to study protocols, their thoughts about the technical and ethical issues involved in using a sham needling device, and their expectations of trial outcomes. The questions were motivated by expressions of concerns the acupuncturists raised in feedback groups during the course of the study, and our desire to improve further trials.

Results: The acupuncturists differed widely in their comfort levels with the research methods used, their adherence to the study protocol, and their expectations of trial outcomes.

Conclusions: We conclude that careful monitoring of acupuncturists, including observation of treatments and frequent meetings to support them throughout the trial, is necessary to maintain a high degree of quality control.

INTRODUCTION

This paper reports the experiences of acupuncturists in a randomized controlled trial (RCT) (n = 135) that compared genuine to sham acupuncture in the treatment of arm pain caused by repetitive use (RSI). The study had a 2-week placebo run-in during which every participant received sham acupuncture using the Streitberger placebo needle. Participants were then rerandomized, without their knowledge, into either genuine or continued sham acupuncture for an additional 4 weeks. The data for this report are based on a written survey and exit interviews of the acupuncturists at the end of the RCT, but before study results were known. The questions focused on their experiences in the study, their adherence to study protocols, their thoughts about the technical and ethical issues involved in using a sham needling device, and their expectations of trial outcomes. Results of the comparison of genuine to sham acupuncture will be reported elsewhere.

MATERIALS AND METHODS

Participating acupuncturists

Twelve (12) licensed acupuncturists from the Boston area were recruited to work in the study during a 3-year period. All were licensed in Massachusetts and were certified by the

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National Commission for the Certification of Acupuncture and Oriental Medicine. They were selected on their clinical and research experience, geographic locations, availability, and willingness to adhere to a research protocol that included sham acupuncture. All acupuncturists were thoroughly trained in the study protocol and use of the sham Streitberger placebo needle by two senior research acupuncturists (R.S., T.K.), and were monitored by a research assistant and acupuncturist (C.M.) throughout the study. Participating acupuncturists ranged in age from 32 to 62 years, two-thirds were female, and their clinical experience ranged from 2 to 26 years, with an average of 10 years. Eight acupuncturists provided the bulk of the treatments (>95%). Five of these had previously performed acupuncture in other RCTs.

The RSI study

The RSI study design required sham needling on all participants during a 2-week placebo run-in period. The run-in placebo period used the Streitberger placebo needle on actual acupuncture points. After the run-in, participants were seamlessly and unknowingly rerandomized to either genuine acupuncture or continued sham acupuncture for an additional 4 weeks of twice-weekly treatments.

Intervention methods: Genuine acupuncture and placebo acupuncture

Acupuncture treatments focused on relaxing the muscles and opening channels to the circulation of of what acupuncturists call *qi*. Point selection in our study was based on the location of the pain, limitations to the range of arm motion, and local sensitivity to palpation. Local channel points proximal to the area of pain were combined with distal points that control the area of pain. Nonmeridian local "trigger" points (*ah shi* points) were included. To incorporate the acupuncture theory of "opening the gates" in pain conditions, all participants received needling on Liver 3 (a point near the big toe) on the contralateral side of the affected arm, which was paired with Large Intestine 4, a point on the hand of the affected arm.[1] If both arms were affected, the latter point was needled bilaterally.

A consensus team of senior acupuncturists selected 20 allowable acupuncture points based upon the acupuncture literature.[2,3] We used a "manualized" approach[4] that allowed some flexibility to vary the location of points according to the specific location and nature of the pain, while providing standardization of treatment. This semiflexible treatment protocol based on TCM included 6 to 10 needles per session applied to local points and selected distal points. Besides the required points, practitioners could select between five and eight additional points at each session and could include local area points traditionally used to affect specific regions (i.e., LI 5, P5, P6, P7, and TW5) and local and distal sensitive *ah shi* points.

During genuine acupuncture treatments, single-use disposable sterile needles (32 gauge, or 0.25-mm diameter) were inserted to standard depth and needled with neutral to moderate stimulation. After obtaining *de qi*,[5] needles were retained for 20 minutes.

The placebo intervention was identical to the true intervention, except that a sham needle device was used . The sham acupuncture device used was the Streitberger needle. This device has been well validated.[2,6,7] In these studies, participants could not distinguish whether true acupuncture needles or the sham device had been used. The sham device is a copper needle handle and a stainless steel shaft with a blunt tip that works like a "magic sword." When the blunt tip is pressed against the skin, the patient feels a slight prick, and the shaft of the needle moves up into the handle. The needle, therefore, "appears" to be inserted into the skin as the shaft shortens. The device is held in place by a small plastic ring, covered with surgical tape or adhesive bandage that supports its vertical position. After training and practice, acupuncturists were quite adept at handling the Streitberger needle, and reported that participants could not tell the difference between real and sham needling. At the end of the treatment period, similar proportions of participants in the genuine and sham acupuncture arms believed they were receiving active treatment (71% versus 81%, respectively, $p = 0.20$).

Both interventions began with disinfection with alcohol and application of a plastic ring fixed with sterile surgical adhesive tape. The sham needle looks and feels like a real acupuncture needle but has a blunt tip that only touches the skin before retracting up into a hollow shaft handle. Sham needles were applied to the same acupuncture points as real needles but without skin penetration. Participants remained with the same acupuncturist throughout entire study. Practitioners were instructed to maintain the exact same procedures and interactions with participants whether administering placebo or true treatment.

No use of massage, heat, moxa, electro-acupuncture, laser stimulation, stretching, or counseling was allowed. No condition other than arm pain could be treated. Acupuncturists were instructed to limit discussions with patients to what was necessary to evaluate the clinical condition at baseline and changes during treatment. Neutral expectations—"this is an experiment attitude"—were expected to be maintained. Before the trial began, all acupuncturists agreed that the protocol was clear and that the planned intervention could be expected to have positive outcomes. All patients signed written informed consent and were told that they might receive genuine or sham acupuncture. As a recruitment and retention incentive, participants who received only sham acupuncture during the study were offered free acupuncture treatments at the end of the study.

All acupuncturists were thoroughly trained in the study protocol, agreed that the protocol was efficacious, and were monitored monthly. Acupuncturists received 5 hours of training including didactic lectures, group discussions, and

specific instruction in the treatment protocols. Didactics included instructions in the purpose of the trial, research methods, integrity in research, use of the sham acupuncture device, possible incidents in the trial, adverse effects reporting, how to respond to patient questions, filling out forms, and ethical considerations. Group discussions during training centered on their feelings and attitudes toward the research protocol and, in particular, the use of using sham needling devices. Practice sessions included using the sham device and applying the manualized, semiflexible acupuncture approach for point selection. An acupuncture monitor (C.M.) observed treatments at various points in the study and a study physician and acupuncture supervisor were available at all times. Completed treatment forms were regularly checked for compliance.

Post RSI study: Qualitative acupuncturist interview study methods

At the conclusion of the trial and before the study outcomes were known, all 12 participating acupuncturists were mailed a questionnaire with a stamped, addressed envelope for its return. The questionnaire was designed to elicit reflections on the acupuncturists' experiences while treating patients with genuine and sham acupuncture needles. All questions were open-ended and required written responses. Our goal was to elicit the acupuncturists experiences rather than limiting their responses to forced choices.

The questionnaire addressed the following issues (Table 1):

1. Use of sham devices including beliefs about subject blinding; technical difficulties using the devices; and any ethical concerns raised by the device.
2. Protocol adherence including any deviations from the study protocol.
3. Beliefs about the sham device's effectiveness and how to explain a participant's improvement when treated with it.
4. Thoughts about the acupuncturist's participation in this RCT or future RCTs.

Participant responses are described for each of these topics.[8]

RESULTS

Eight (8) of the 12 surveys mailed out were completed by the acupuncturists and returned. Two acupuncturists moved from the area and did not complete the survey; two others did not respond. Surveyed acupuncturists ranged in age from 32 to 58 years; 3 were male and 5 female; all had postgraduate training in acupuncture from the New England School of Acupuncture in Watertown, Massachusetts. Five had had previous experience working in other acupuncture RCTs. Results are grouped according to the survey topics. Verbatim quotations are provided where they effectively illustrate important points.

Use of sham devices

Most acupuncturists became comfortable with using the Streitberger sham devices during the study. Only one reported technical difficulties, stating that the devices could fall apart when handled. However, several acupuncturists had complex feelings about the use of sham needling and used various strategies to cope with ethical questions that arose while administering sham treatments. In particular, they felt significant tension between their patient-focused acupuncture training and their roles as scientific investigators. Even though they were fully aware that they would be asked to administer sham treatments in the study, they reported feeling deceitful when they did this. One acupuncturist noted feeling "quite hypocritical" using the sham device because it went against "honorable intentions" and "commitment to treatment results." Discomfort led another acupuncturist who responded to our survey to drop out of

Table 1. Acupuncturist Survey: Post-RSI Trial

- What was your experience when people got better from placebo (if they did)?
- To what extent did the parameters of the trial interfere in the patient–practitioner relationship (manualization of the trial, use of the placebo needle)?
- If these parameters (above question) significantly interfered, do you believe this interference compromised the benefit that the patient received from acupuncture?
- Do you believe that participants in the study were aware of the placebo needles? Why?
- Are you aware of anything you might have done inadvertently that may have indicated to the patient whether they were receiving (real or sham) treatment?
- Would you be willing to participate as a treatment provider in another placebo-controlled trial?
- In terms of the scientific statistical outcomes: What do you think the outcome will be? Will acupuncture outperform the sham or will they be the same?
- If the outcome shows that genuine acupuncture performs better than sham acupuncture, what would you think? How would you explain this?
- If the outcome shows acupuncture performs the same as sham acupuncture, what would you think? How would you explain this?
- If the outcome shows sham acupuncture performs better than real acupuncture, what would you think? How would you explain this?
- In terms of your practitioner experience (not having anything to do with statistics): Do you think that most of your patients improved?
- Do you think that those treated with real acupuncture improved more than those you treated with sham acupuncture?
- What do you think motivated patients in the sham group to continue coming in for treatments?

the study after completing treatment of more than 20 participants. This acupuncturist felt it was unethical to "render placebo treatment to clients who thought they were getting 'real' treatment and who were in tears and debilitated with pain." Ultimately, the latter "troubling concern . . . influenced my decision to stop participation."

Protocol adherence

Despite thorough training in the trial protocol, all respondents reported feeling challenged by their work as investigators as opposed to their "normal" roles as clinicians. Although all agreed that the protocol was reasonable at the outset, in particular, they still felt strong urges to apply the typical tools of their clinical practices such as active needling, heat, external herbal treatments, treatments for the "whole" person, and counseling. (To our best knowledge, none of them acted on these urges.) During monitoring interviews, many acupuncturists indicated how difficult it was not to be permitted to offer dietary, ergonomic, or physical advice to the participants. Several acupuncturists reported that they frequently hoped that participants would be randomized to the genuine acupuncture group after the placebo run-in had been completed. In one instance, an acupuncturist actually called the clinical coordinator and requested that a patient be re-randomized to the genuine treatment group. Unwilling to comply with the rigors of RCTs, this acupuncturist (whose responses are included here) was not assigned to treat more participants in the study.

Although 12 acupuncturists were originally trained for the RCT, 5 did not stay with the trial for its entire course. Study coordinators ceased assigning participants to 3 acupuncturists because they broke the protocol (e.g., for using nonprotocol points in the active phase, failing to keep accurate records, or for being unclear about the study's procedures.) Two (2) other acupuncturists resigned from the trial: 1 because of the ethical concerns with administering the sham treatment and the other because of re-locating out of the state. (In the interest of improving further trials, all 12 acupuncturists were sent a survey and given the opportunity to respond. Eight (8) responded, including the acupuncturist who resigned.)

Beliefs about the use of sham interventions

Acupuncturists reported feeling perplexed when trial participants improved with sham acupuncture. To assuage their discomfort, some focused special attention on participants in the sham group. For example, one wrote, "I found my intention of treatment was there whether I was using real or sham acupuncture. I wanted people to get better no matter what I used. I think this influenced my results." Another noted needing to focus on inner resources to transmit healing: "I suspect that if I am to get good results with placebo needles I must cultivate *qi*." (*Qi* can be loosely translated as a natural force or energy circulating in the body.) This individual admitted that he/she was possibly working against the scientific construct of the RCT in favor of patient care by using good intentions to try to enhance healing. Yet another acupuncturist noted feeling "doubtful of acupuncture as a modality" when participants improved with sham acupuncture, and feeling "demoralized" when the sham appeared to outperform the genuine treatment.

Intention was an important consideration for all practitioners, and some thought they could compensate for sham needling and influence results via increasing their conscious or unconscious wishes, alliance, and connection with participants. Some believed that the participants expectation and hopes that they were in the active group played a role in their improvement. All acupuncturists had agreed to the role of investigators, including the Traditional Chinese Medicine (TCM)-based protocol and sham intervention, at the trial outset, but over time, some became increasingly uncomfortable with the perceived deception and their role in the scientific investigation. Several reported that they dealt with their discomfort by reminding themselves that all patients in the sham group would receive real acupuncture at the end of the study. As one said: "At first, I was frustrated by the constraint of using sham needles, but I felt better after awhile knowing that patients would receive genuine acupuncture following their participation."

Expectations about the trials' outcomes

When asked whether they expected that genuine acupuncture would outperform sham, the acupuncturists' responses were evenly split. Half expected that real acupuncture would outperform the sham intervention; the other half believed the results of real and sham acupuncture would be about the same. Reasons varied. One practitioner asserted that the sham devices, because they touch the body and are metallic, would "stimulate energy on the surface of the skin, clearing congestion and pain in connective tissue on the surface of the body" and creating a small stimulus that was enough to have a positive treatment effect. Therefore, it was much like "contact needling" (or "noninsertion acupuncture"), and could have the therapeutic effects of shallow needling. One practitioner commented that "the needles do come in contact with the body and thus come into contact with the *qi*." Another believed that the act of simply palpating the arm for treatment points was enough to create some positive therapeutic effects. Although all acupuncturists were trained in TCM and agreed to the TCM-based protocol, it is interesting to note that half of the acupuncturists who responded to our survey regularly incorporate Japanese-style acupuncture into their practices. These styles may include techniques of superficial and/or contact needling. Although no one thought the sham needling was a genuine form of acupuncture, this may explain some of their responses regarding the potential therapeutic effect of simply touching the points, and raises issues for other trials in improving the use and placement of devices such as the Streitberger needle.

Overall thoughts about involvement in the trial

Acupuncturists reported many positive experiences from their participation in the study, including the chance to focus on RSI arm pain, being part of a dynamic research group, and the opportunity to challenge themselves as both healers and researchers. "It was a tremendous opportunity which raised my thinking about patient–practitioner relationships, research protocols, and the power of the placebo," noted one acupuncturist. A common feeling was that, overall, the experience was a challenging one that offered valuable opportunities for them to develop further professionally. Even though the trial was challenging on many levels, only 2 of the 8 acupuncturists who responded reported that they would not take part in another trial involving sham and genuine acupuncture.

CONCLUSIONS

Our experiences in training and working with acupuncturists during the study raise many important issues for the smooth functioning and quality control of future acupuncture trials. Acupuncturists need to be aware of the dilemmas inherent in rendering sham interventions, using devices such as the Streitberger placebo needle and adhering to study protocols. To the maximum extent possible, these dilemmas should be anticipated at the beginning of the trial and careful training should be provided. Ongoing supervision is critical. Discussions of ethical issues and likely emotional challenges from working in a placebo-controlled RCT need to be at the forefront of training.[9] All acupuncturists need to understand that acting as investigators is a challenge and that following a set protocol and administering sham treatment are situations very different from clinical practice.

Frequent monitoring of acupuncture point selection, record keeping, and interactions between acupuncturists and study participants is an important complement to thorough initial training. Monitoring can be done via video or audio recordings (with ethical approval), with frequent visits by a study monitor, and by having acupuncturists observe each other. Scheduled meetings of the team acupuncturists to share strategies and support are essential. Regardless of coordination and scheduling challenges, the use of a few well-trained acupuncturists to provide the treatments is preferred over having many acupuncturists treating only a few study participants each. Acupuncturists must be committed to the process of research itself, forewarned about the challenges of acting as investigators administering sham interventions, and committed to the overarching research questions being investigated.

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