



Contents lists available at ScienceDirect

## Journal of Integrative Medicine

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[www.journals.elsevier.com/journal-of-integrative-medicine](http://www.journals.elsevier.com/journal-of-integrative-medicine)



## Commentary

## Delivery of acupuncture in clinical trials: Research acupuncturists' perspectives

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## ARTICLE INFO

## Article history:

Received 4 August 2022

Accepted 20 October 2022

Available online 30 March 2023

## Keywords:

Acupuncture

Traditional Chinese medicine

Clinical protocols

Health knowledge, attitudes, practice

Researcher-subject relationship

Placebos

## ABSTRACT

Delivery of acupuncture in the setting of a clinical trial is a unique practice that diverges significantly from the delivery of acupuncture in a real-world clinical setting. Research acupuncturists, particularly those trained in traditional Chinese medicine (TCM), are often required to set aside valued precepts of traditional care, including diagnosing imbalances, individualizing treatment, and forging a therapeutic relationship with patients. TCM-trained acupuncturists express mixed feelings about participating in clinical trials. Many are eager to play a vital role in the advancement of acupuncture science and appreciate the need for strict protocol adherence to minimize bias. However, the acupuncturist(s) may also have concerns about clinical trial methodology, including but not limited to the delivery of a control condition, e.g., sham acupuncture. Investigators should anticipate certain questions and even a level of resistance to the requirements of research among acupuncturists and be prepared to address them. This manuscript presents a brief review of the subjective experience of the research acupuncturist within the available scientific literature as it pertains to the delivery of active and sham clinical research protocols. Our goals are to better understand the perspectives of acupuncturists who may participate in clinical research, so that their concerns may be addressed in study design and methodology. To that end, we suggest the creation of a novel training program specifically for clinical trial acupuncturists, intended for qualified TCM- and Western-trained practitioners, that would help to standardize the research acupuncturist's role and help to strengthen the design and execution of acupuncture studies.

Please cite this article as: Anastasi JK, Capili B, Neumaier J, Hackett L. Delivery of acupuncture in clinical trials: Research acupuncturists' perspectives. *J Integr Med.* 2023; 21(4):315–319.

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## 1. Introduction

Randomized controlled trials (RCTs) are widely considered the gold standard for evaluating the merits of medical therapies, including acupuncture and other treatments under the umbrella of complementary and alternative medicine (CAM) [1]. In the evaluation of acupuncture, traditional Chinese medicine (TCM)-trained acupuncturists (also called licensed acupuncturists) play a central role in the precision delivery of acupuncture (active) and sham (inactive) treatments in accordance with a preset research protocol. (Please note that for this discussion, “TCM-trained” and “licensed” acupuncturists are used synonymously; “medical” acupuncturists are medical doctors (MDs) trained in acupuncture, and “research” or “clinical trial acupuncturists” are practitioners who perform acupuncture in clinical trials whether TCM-trained or medical.)

Many are eager to participate in clinical trials to build a body of knowledge that supports their profession and underscores its value within healthcare around the globe.

The delivery of acupuncture in the context of a clinical trial may be different from its delivery in the context of clinical care. For example, in real-world practice, acupuncturists base their patient's treatment needs, including acupuncture point selection, on their presentation at the time of the visit; they reassess the patient and may modify treatment at subsequent sessions based on their observations as well as feedback from the patient. By contrast, in clinical trials, point selection is determined by the study design team in advance of the patient visit and outlined in a protocol; the protocol is subject to less (or sometimes no) flexibility among patients and between sessions. Also, for “blinding” (acupuncture trials are typically “single-blinded,” meaning patients are not made aware of which treatment they are receiving) and to control for a range of variables, acupuncturists may also be required to minimize communication with the subject during the visit. Thus, they do not provide a therapeutic relationship or offer the full comple-

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ment of care (such as herbs and discussions about diet and lifestyle modification). They must also knowingly administer sham treatments.

It is vital that clinical trial acupuncturists feel comfortable delivering a modified version of their craft so that their invaluable contribution is honored, and the study's integrity is preserved [2–4]. In addition, although they are uniquely positioned to shed light on controversies and challenges surrounding the use of RCTs for the evaluation of CAM therapies, holistic systems, and acupuncture specifically, licensed acupuncturists' perspectives are infrequently sought [1,2,5–7].

The present manuscript discusses the subjective experience of acupuncturists as it pertains to the delivery of active and sham clinical research protocols. Further, we propose the creation of a novel orientation program (and possibly credentialing) for clinical trial acupuncturists to delineate, expand, and, to some extent, standardize their unique and critical role in the advancement of acupuncture science.

## 2. Research acupuncturist's perspectives

### 2.1. Perspectives about holistic and individualized treatment

When asked about their experiences, research acupuncturists sometimes describe a disconnect between the delivery of acupuncture in clinical trials and in TCM practice [2–5]. A main difference relates to the individualization and flexibility of acupuncture within TCM, where diagnoses relate to observations at the time of presentation and are not necessarily static; and treatments may vary from one visit to the next [2,3]. A licensed acupuncturist characterized TCM treatment as “finding the right key for the right lock [since] the individual is more important than the condition” [6]. A second major difference is that TCM is fundamentally holistic, meaning that human health is understood as deriving from a whole working system that is inseparable from nature, rather than from a system of isolated parts [8].

As a succinct overview, diagnosis within TCM is precise but fluid, and is based upon observation of underlying energetic imbalances indicated by a patient's health history and a physical examination. A patient's complaints are explored in the context of whole body functioning, including sleep, appetite, bowel movements, and urination, with importance placed on daily living habits such as ergonomics, diet, recent life changes and emotional stressors [3,9]. An acupuncturist's physical examination may include palpating the pulse and observing the appearance of the tongue, using evaluative criteria that are not a part of Western medicine. The objective is to detect the underlying imbalance or “syndrome” that led to the development of symptoms, for example, excess, deficiency, or stagnation of Qi within the liver, kidney or spleen, or as caused by excess heat, cold or dampness [9]. Therapeutic interventions include herbs and a series of acupuncture treatments to correct the imbalance or pattern of disharmony in the body. The number and anatomical location of acupuncture points may vary from one session to the next according to patient feedback and response [3]. Further, the details of needle placement are informed by the specific acupuncture tradition and training and may be influenced by the individual practitioner's clinical experience.

By contrast, an RCT requires practitioners to apply acupuncture at predetermined points based on a fixed protocol without evaluating the patient, diagnosing current imbalances, and individualizing the treatment according to the principles of their training. The usual holistic purview of a TCM-trained practitioner must narrow considerably to include only considerations relevant to the protocol. Research patients are evaluated at each visit to assess for adverse events, but not typically to inform point selection, unless

there is some built-in flexibility to the protocol. In most academic studies, the criteria for patients to be included in the trial starts with a standard biomedical diagnosis, for example, migraines or peripheral neuropathy, which describes a homogenous group by Western methods, but a heterogenous group (meriting different treatments) by TCM standards [10].

When not properly oriented to the rigors of clinical trial involvement, practitioners may find it challenging to adapt their normally broad-viewed, responsive practice style to the fixed protocol required in RCTs. They may be tempted to add interventions, such as heat, herbs, or counseling, in accordance with their usual habits of clinical care [4]. Also, they may harbor a concern that the study results will lack meaning—particularly if negative, but also if positive—due to differences between the protocol and the way they typically practice [2,6].

### 2.2. Perspectives on patient interaction

TCM practitioners place great importance on the healing potential of a genuine relationship with patients. Many believe that two-way communication enables them to establish rapport, set expectations, and outline a kind of contract that helps patients to relax and trust the process. They “work on the case together,” offering information and advice so that patients can make sense of their condition and take an active role in their own recovery, also listening to feedback offered by the patient [3,6].

The interactive aspect of the medical ritual may play a role in healing via the “placebo effect” [11]. A placebo, of course, is a substance used in clinical trials that is considered inert or inactive, for example, a sugar pill, that serves as a basis for comparison against the active substance being tested. When what is being tested is not a pharmaceutical but a manual procedure such as acupuncture, the “placebo” is called a “sham” treatment. A sham procedure is designed to recreate the movements and possibly induce some nonspecific sensory effects of the active procedure, so that it is indistinguishable to the patient, but does not induce the therapeutic effect [11]. For a trial to be successfully blinded, sham acupuncture may involve inserting needles at “non-acupoints” and/or at shallow or nonpenetrating depths [12].

Despite evidence to the contrary, skeptics of acupuncture have suggested that acupuncture-induced analgesia relates to a “placebo effect” rather than a therapeutic one [12,13]. Indeed, it is not uncommon for patients in the placebo arm of clinical trials (including patients treated with sham acupuncture in acupuncture clinical trials) to experience improvement of symptoms and, in particular, pain relief [13,14]. Furthermore, according to theories, the brain can modulate incoming pain signals from real and penetrating sham acupuncture using different pathways [12,15].

Recognizing the difference between a “placebo effect” and a “placebo response” may help clear up confusion as it pertains to acupuncture trials, where therapeutic and placebo effects may co-exist. A “placebo effect” is a psychobiologic response to treatment with a placebo or sham procedure and may include changes in patient-reported symptoms or quality of life. By contrast, a “placebo response” is objectively measurable clinical improvement attributable to a placebo [16]. A recent meta-analysis of RCTs of acupuncture for the treatment of functional dyspepsia revealed that patients treated with a sham procedure experienced symptom relief and improved quality of life, important subjective “placebo effects.” However, only subjects treated with real acupuncture experienced objective improvements in gastrin secretion and heart rate variability, i.e., there was no evidence of a “placebo response” [16]. Another way of understanding the results is that sham acupuncture provided some but not all of the therapeutic value of real treatment.

In addition to mechanisms related to needling, human interaction with an attentive provider may underlie some of the improvements seen in patients receiving placebo treatments. In research, in order to control for the “placebo effect” stemming from the human factor of the interaction, verbal interactions are restricted [17]. Talking is limited to a short script; any issues that arise during the session that might require spontaneous interaction are addressed without speaking if possible or may be directed to a monitor who is also present in the room [17]. The impersonal style required to reduce bias in research may feel particularly counterintuitive to TCM-trained practitioners and take some getting used to.

### 2.3. Perspectives on administering sham treatments

As stated, sham procedures used in acupuncture research are designed to be indistinguishable from active treatment from the patient’s point of view and not cause the treatment effect. Even when research acupuncturists are clear about the importance of administering sham in RCT design at the onset, they may find it challenging once the trial is underway [2,18,19]. They may have the nagging feeling that they are “deceiving” the patient, “betraying” their trust, or simply wasting their time, feelings they may not encounter in their capacity as healer [2,4]. In one of the few qualitative studies of acupuncturist perceptions of clinical trials ( $N = 12$ ), one lobbied for their patient to be re-randomized from the sham to the true treatment group (and was dismissed from participating as a result); another dropped out of the study citing concern over the ethics of administering placebo [4]. Some stated that they set a mental intention that their patients get relief whether in the active treatment or sham group [4]. Even experienced researchers must remind themselves to maintain a neutral affect when a patient they know is randomized to receive sham treatment [19].

While the instinct to be forthcoming with patients and administer active treatment runs deep, and is of course ethical and valuable in clinical care, controlling for that instinct in a clinical trial setting is necessary and good practice. Pre-trial orientation and education, as well as check-in meetings over the course of the clinical trial period, may help research acupuncturists gain clarity around the differences between the roles of healers and researchers and avoid conflating the two [2]. Also, research acupuncturists may be reassured to learn that it is not uncommon for sham-treated patients to derive benefit from their participation. Firstly, patients in both treatment and sham groups report enjoying the chance to lie down, relax, and receive individual attention from a provider, which may also contribute to a placebo effect [2]. Secondly, patients randomized to the control group may be offered the same course of acupuncture given to the “true” group once the trial is unmasked [4,17]. And thirdly, patients who receive sham acupuncture may still improve considerably due to a “placebo effect” [2,19,20]. A focused review of a Cochrane meta-analysis revealed that clinical trial patients who received a “physical placebo” had a stronger placebo response than did patients who received a “pharmaceutical placebo” in separate clinical trials. And the placebo response among patients treated with sham acupuncture was statistically stronger than that from other various physical sham treatments, for example, chiropractic treatment or transcutaneous nerve stimulation [20].

Mechanisms underlying the placebo effect of sham treatments are of great interest. There is evidence to suggest that a patient’s expectation of relief from the treatment triggers release of pain-relieving neurochemicals in the brain, including opioids, cannabinoids and dopamine [21]. Analgesia derived from acupuncture may relate to acupuncture specific as well as nonspecific effects [22].

## 3. Optimizing and expanding acupuncturist involvement in RCTs

### 3.1. A growing need

By multiple objective measures, the field of acupuncture is enjoying a surge in popularity. The last two decades have witnessed an increased interest among patients, providers, and researchers in the use of acupuncture for symptom relief, disease treatment, and wellness [23,24]. A PubMed search of the term “acupuncture” yielded nearly 30,000 published articles between 2002 and 2022, including nearly 5000 RCTs [25]. Research funded by the National Institutes of Health in the United States alone has contributed greater than 1200 articles to the literature; globally, 236 privately or publicly funded clinical trials evaluating acupuncture are currently underway [23,26]. As positive results amass, governmental and medical specialty groups in North America, Europe, and Australasia have incorporated acupuncture into their official clinical treatment guidelines for a range of pain and non-pain indications [27].

The growing volume and improved quality of acupuncture research owe in part to the development and implementation of the *Standards for Reporting Interventions in Clinical Trials of Acupuncture* (STRICTA), a checklist of guidelines compiled in 2001 and revised in 2010 [28]. STRICTA guidelines encourage greater detail and transparency in reporting, which facilitates thoughtful analysis of results and uniformity and repeatability of design [29]. To be in STRICTA compliance, the reporting of an acupuncture clinical trial must elucidate 6 items of the study: (1) treatment rationale, (2) details of needling, (3) treatment regimen, (4) other components of treatment, (5) practitioner background, and (6) comparator intervention [29]. Seventeen details (sub-items) are required: (1a) style of acupuncture; (1b) reasoning upon which treatment is based, with references where appropriate; (1c) extent to which treatment was varied; (2a) number of needle insertions per subject per session (a range of the number of needles and mean number); (2b) names or location of points; (2c) insertion depth; (2d) physiologic response sought; (2e) needle stimulation; (2f) needle retention time; (2g) needle type; (3a) number of sessions; (3b) frequency and duration of sessions; (4a) details regarding adjunctive treatments (e.g., moxibustion); (4b) treatment setting and context, including information and instructions to patients; (5) practitioner description, including qualifications and years in practice; (6a) rationale for comparator or control intervention; (6b) detailed description of comparator or control intervention. Descriptions and examples of each of the sub-items have been published to further assist acupuncture researchers [29].

In the US, public demand for acupuncture is also steadily increasing and mirrors important trends including the need for effective alternatives to opioids in the treatment of pain [24,30]. Other trends include increased availability of acupuncture at community and academic centers (particularly for the treatment of musculoskeletal and oncologic pain), the inclusion of acupuncture in treatment programs at the Veterans Health Administration, and compensation through Medicaid (for back pain) and a small but growing number of private health insurance companies [24]. Also, more allopathic physicians are becoming trained in acupuncture, termed “medical acupuncture,” and adding it to their therapeutic repertoire [24].

While acupuncture is practiced in the West and increasingly recognized as legitimate, broader implementation has been limited by several factors [9]. First, acupuncture is still widely misunderstood in the West, because the philosophies underpinning TCM and allopathic medicine are fundamentally different. Allopathic medicine sees individuals as a complex machine made of intercon-

nected parts and characterizes disease according to specific outward patterns of symptoms, signs and pathologic findings. Diagnosis relies heavily on imaging and laboratory evaluation and increasingly less on observations made during physical examination. Treatments aim to attenuate or compensate for observed pathology, either physically via surgery or biochemically via pharmaceuticals, and rarely address the underlying cause.

By contrast, as discussed, TCM views individuals as fundamentally whole and integrated with nature and understands disease as patterns of imbalanced or blocked energy, or qi (which has no parallel in Western medicine) [9]. Diagnosis is undertaken to deduce an individual's root pattern of disharmony or imbalance (called a "syndrome") and relies on data derived from a comprehensive health history, including medications, psychosocial and lifestyle-related factors, and a physical examination that focuses on tongue and pulse properties. TCM treatment aims to regulate qi and restore its flow along natural meridians in the body; it is subtle, multifaceted, and highly tailored to each patient's specific circumstances and presentation [6].

Thus, despite a favorable public opinion, and historic, experiential, logic-based, and research-based evidence to the contrary, Western-educated practitioners may dismiss TCM as irrational, esoteric, and inferior to the style of medicine that they were taught [6]. A more convincing body of scientific evidence demonstrating the effectiveness of acupuncture is necessary to counter this view.

Second, as outlined above, there are unique challenges in applying Western scientific principles to the modality of acupuncture [1,6,9]. According to licensed acupuncturists, key clinical trial practices that contrast with traditional Eastern practices include: the use of a biomedical diagnosis as opposed to TCM-based diagnosis, isolating a single aspect of a patient for treatment, not individualizing treatment, limiting provider-patient interaction, and not building a therapeutic relationship.

Another suite of variables that must be managed for meaningful clinical trial results is variability in technique among the practitioners, which may differ according to training, experience level and personal style. Some style differences may include needle type, depth and duration of needle insertion, and needle manipulation, all or any of which might affect outcomes [7]. Even when well trained and instructed, small interventional differences between practitioners may occur and introduce an element of bias [2]. Following STRICTA reporting guidelines and performing more trials will help clarify the influence of various acupuncture practice parameters on treatment outcomes.

Incorporating licensed acupuncturists into early stages of study and protocol design, not just relying on them to administer study treatments, may help to mitigate objections, smooth the inherent friction between divergent methodologies, and improve trial design and execution. Some licensed acupuncturists maintain that RCTs are not suitable for the study of acupuncture and that the current body of evidence does not reflect real-world effectiveness. However, many believe that RCTs are central to improving acupuncture's acceptance, particularly among skeptical patients, medical acupuncturists, and their Western-trained colleagues, and that more robust RCTs are urgently needed [1–6,9].

### 3.2. An educational program for research acupuncturists

Many licensed and medical acupuncturists in the West and in China understand and appreciate the need for RCTs to demonstrate acupuncture's efficacy and to support expanding its use within mainstream medicine [2,4,18]. To them, the delivery of acupuncture within clinical trials is a distinct art. A majority of clinical trial acupuncturists say that they enjoy it, citing the collegiality among team members, treating a broader demographic of patients, and contributing to advancing the science of acupuncture as particu-

larly satisfying [2]. Some like that the research protocol is easier and faster to perform, compared with the individualized approach they practice in their offices [2]. Most would welcome the opportunity to participate in additional trials [2,4]. Advanced acupuncture providers are increasingly important to clinical trials, and may take on multiple roles, including participating in recruitment and consent, project coordination, adverse event monitoring and management, and study design [31–34].

It is our impression that licensed acupuncturists want to play a greater role in clinical research, and the field would benefit from their involvement beyond the role of needling. We envision a program for the education of a new category of a medical professional—the research acupuncturist—that would address the aforementioned issues, empower TCM-trained acupuncturists to participate effectively and more broadly in clinical trials, and ultimately improve the ease, reliability, reproducibility, reporting and overall quality of acupuncture research.

The program would strive to meet the following objectives: to teach scientific philosophy and research methods, to clarify differences between TCM medical care and research acupuncture, to help practitioners shift their mindset from short-term healing to long-term discovery, to emphasize the importance of strict protocol adherence, to screen for and unpack resistance to study participation related to the need to modify their usual style of practice, to teach practitioners how to administer sham therapies, to assess skill proficiency including sound needling technique, and to position graduates for broader involvement in study design and monitoring.

Participants would be required to pass written and practical examinations for credentialing. Resources for ongoing professional development and community-building for research acupuncturists may be developed, such as continuing education opportunities, online peer-to-peer dialogue, and academic and private clinical trial job listings.

## 4. Conclusion

Challenges associated with studying acupuncture may be a major reason that the field is undervalued and under-prescribed. TCM-trained research acupuncturists are uniquely positioned to help resolve these challenges and evolve the evidence base that underlies the practice of acupuncture within Western medical practice. By involving acupuncturists with advanced training at the early stages of study development would draw on their unique insights and improve study design. A specific program intended to address research acupuncturist's concerns, empower expanded participation, and define a standard of practice would be useful toward advancing the field of clinical acupuncture and broadening implementation.

## Funding

This study was funded by the National Institute of Nursing Research of the National Institutes of Health (No. R01-NR017917).

## Authors' contribution

JKA is the PI of the parent study, developed content, wrote, and edited the manuscript. BC synthesized content and edited the manuscript. JN edited the manuscript. LH contributed to content development and synthesis. All authors contributed to the discussion of the data and of the manuscript.

## Acknowledgments

Research reported in this manuscript was supported in part by the National Institute of Nursing Research of the National Institutes of Health (No. R01-NR017917). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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