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Methods to Standardize a Multicenter Acupuncture Trial Protocol to Reduce Aromatase Inhibitor-related Joint Symptoms in Breast Cancer Patients

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Abstract

Robust methods are needed to efficiently conduct large, multi-site, randomized controlled clinical trials of acupuncture protocols. SWOG S1200 is a randomized, controlled sham- and waitlist-controlled trial of a standardized acupuncture protocol treating aromatase inhibitor (AI)-associated arthralgias in early stage breast cancer patients (n=228). The primary objective is to determine whether true acupuncture administered twice weekly for 6 weeks compared to sham acupuncture or a waitlist control causes a reduction in AI-associated joint pain at 6 weeks as assessed by patient report. The study is conducted at 11 institutions across the US. The true acupuncture protocol was developed using a consensus-based process. Both the true acupuncture and sham acupuncture protocols consist of 12 sessions administered over 6 weeks, followed by 1 session per week for the remaining 6 weeks. The true acupuncture protocol uses standardized protocol points in addition to standardized acupoints tailored to a patient's joint symptoms. The similarly standardized sham acupuncture protocol utilizes superficial needling of non-acupoints. Standardized methods were developed to train and monitor acupuncturists, including online and in-person training, study manuals, monthly phone calls, and remote quality assurance monitoring throughout the study period. Research staff was similarly trained using online and in-person training, and monthly phone calls.

Keywords

Acupuncture; aromatase inhibitors; breast cancer; clinical trial; multi-site; randomized controlled trial

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Introduction

To date, there have been a limited number of multi-site, large-scale randomized controlled trials of a standardized acupuncture protocol. In this manuscript, we describe the methods used to develop and maintain quality assurance of the acupuncture and sham acupuncture protocol in a multi-site, large-scale randomized sham- and waitlist-controlled trial testing the effects of a standardized acupuncture protocol on reducing joint pain associated with aromatase inhibitors (AIs) among early stage breast cancer patients. AIs are widely prescribed to postmenopausal women for the treatment of hormone-sensitive breast cancer, and have been shown to be effective and improving disease-free survival.[1–6] However, a large number of women develop joint pain and arthralgias following AI initiation and many discontinue AI treatment due to side effects. No treatments have been identified that successfully prevent or treat AI-associated arthralgias.

Results of two prior small trials conducted by our group suggest that acupuncture may be beneficial in treating AI-associated arthralgias. The first study was a waitlist-controlled trial (n=21) of a 6-week course of full body and auricular acupuncture among postmenopausal women with AI-associated arthralgias.[7] Improvements were reported in pain severity, pain-related functional outcomes, and physical well-being, with no significant adverse events reported. However, the study was limited due to the small sample size and lack of a blinded control group. The second study was a randomized, blinded, sham-controlled trial (n=38) of a 6-week course of full body and auricular acupuncture among postmenopausal women with AI-associated arthralgias.[8] The sham acupuncture arm utilized superficial needling at non-acupuncture points. Investigators and patients were blinded, but not the acupuncturists. Compared to the sham arm, patients who received true acupuncture reported a 50% decrease in mean Brief Pain Inventory-Short Form (BPI-SF) scores and similar changes were observed with Western Ontario and McMaster Universities Osteoarthritis (WOMAC) and Modified-Score for the Assessment and Quantification of Chronic Rheumatoid Affections of the Hands (M-SACRAH) scores. These prior results suggest that acupuncture is an effective and well-tolerated strategy for managing AI-associated arthralgias. However, both previous studies involved a single acupuncturist at a single institution. A large-scale multi-site trial is needed to test the effects of the protocol on reducing AI-associated arthralgias among a more diverse population of patients, in a variety of clinical and institutional settings, and implemented by multiple acupuncturists with differences in acupuncture training.

Prior multi-site acupuncture trials have used standardized protocols and have trained multiple acupuncturists to implement the protocol. These studies have included up to 638 patients treated at up to 37 institutions[9–15] and acupuncturists were trained in person by the investigator teams (personal communication, Karen Sherman and Claudia Witt). To our knowledge, prior studies have not developed methods to train and monitor acupuncturists remotely. New, robust methods to train acupuncturists to implement clinical trial protocols are needed to efficiently conduct large-scale acupuncture trials.

Materials and Methods

Trial Design Overview

SWOG S1200, *Randomized Blinded Sham- and Waitlist-Controlled Trial of Acupuncture for Joint Symptoms Related to Aromatase Inhibitors in Women with Early Stage Breast Cancer*, is funded by the US National Institutes of Health's (NIH) National Center for Complementary and Integrative Health (NCCIH), National Cancer Institute (NCI) and Office of Research on Women's Health (R01 AT006376). The study is being conducted within the SWOG NCI Community Oncology Research Program (NCORP) Research Base (1UG1CA189974-01) (www.swog.org/Visitors/AboutUs.asp). SWOG's network includes more than 4,000 researchers at more than 650 institutions, including 24 NCI-designated cancer centers and additional international cancer centers. S1200 is a limited institution trial that is currently open at 11 institutions for a total of 28 clinical sites within the SWOG network.

S1200 is a 52-week, 3-arm trial using a 2:1:1 ratio to true acupuncture vs. sham acupuncture vs. waitlist control (see Figure 1). Patient randomization is dynamically balanced by study site to account for potential outcome differences related to the discrete acupuncture administration approaches. A total of 228 patients are expected to be recruited.

Patients in the true acupuncture arm receive true acupuncture twice weekly x 6 weeks (12 sessions), followed by weekly true acupuncture x 6 weeks (6 sessions). Patients in the sham acupuncture arm receive sham acupuncture twice weekly x 6 weeks (12 sessions), followed by weekly sham acupuncture x 6 weeks (6 sessions). Patients in the waitlist control arm remain in the waitlist condition for the full 12 weeks. As incentives for trial participation and to increase patients' willingness to be randomized to either the sham or waitlist control condition, at 24 weeks, all patients receive vouchers for 10 true acupuncture "bonus" sessions to be used by the 52 week study visit. Data are collected at baseline, 2, 4, 6, 12, 16, 20, 24 and 52 weeks (see outcome measures below). Patients, study staff and study clinicians are blinded to randomization condition for patients randomized to the true and sham acupuncture conditions; only the study acupuncturists, the SWOG central statistical center, and one lead site (Columbia) study coordinator are aware of the randomization assignment.

Study Objectives

The primary objective of the S1200 trial is to determine whether true acupuncture administered twice weekly for 6 weeks compared to sham acupuncture and waitlist control causes a significant reduction in joint pain related to aromatase inhibitors (AIs) in women with early stage breast cancer as measured by the Brief Pain Inventory-Short Form (BPI-SF) worst pain score at 6 weeks. A secondary objective of the S1200 study is to investigate the effects of true acupuncture administered twice weekly for 6 weeks followed by 6 weekly maintenance treatments compared to sham acupuncture and waitlist control in this study population. Additional secondary objectives will evaluate the effects of acupuncture on self-reported pain, joint stiffness, quality of life, functional testing, AI adherence and pain

medication use over the 52-week study period, as well as serum hormones and inflammatory markers, and the safety of acupuncture within this population.

Eligibility Criteria, Recruitment and Consent

Eligibility criteria were selected to identify postmenopausal women with a history of early stage hormone receptor-positive breast cancer who developed or had a worsening of joint pain and/or stiffness after initiating AI therapy. Ineligibility criteria included women who had underlying joint disease or trauma, use of analgesic medication or recent exposure to acupuncture that could confound study results. Trial participants are identified and recruited at each clinical site by clinical and research staff. All participants provide written consent. Institutional Review Board approval was obtained by all participating institutions prior to trial initiation.

Results

Acupuncture Protocols: True Acupuncture and Sham Acupuncture

Acupuncture Protocol Development—The acupuncture study interventions were developed by a consensus of acupuncture experts and were based upon our previous studies of acupuncture for AI-related arthralgias with adherence to the Standards for Reporting of Controlled Trials in Acupuncture (STRICTA) recommendations.[16] The consensus process involved surveying 12 acupuncturists who had treated oncology patients for at least 5 years. The acupuncturists completed a questionnaire on a variety of treatment principles and acupuncture point protocols, including open-ended questions on their practice style. The true acupuncture point protocol was then derived based on consensus with respect to traditional Chinese medicine differential diagnosis, treatment principles and point prescriptions.

True Acupuncture Protocol—Both the true and sham acupuncture treatments consist of twelve, 30–45 minute sessions administered over a period of six weeks (2 sessions per week) followed by one session per week for the remaining six weeks. True acupuncture treatment is semi-standardized. Table 1 displays the true acupuncture point protocol. The point prescription is based on a standard Traditional Chinese Medicine point prescription to treat “Bi Syndrome” and the National Acupuncture Detoxification Association (NADA) protocol applied to one ear to relieve pain and decrease stress. At every true acupuncture visit, the patients assigned to true acupuncture will receive the full body acupuncture prescription and the auricular acupuncture-NADA protocol in one ear (to be alternated at each visit). The needles remain *in situ* for 20–25 minutes during which the study acupuncturist returns to stimulate the needles once, utilizing even needle technique in order to re-elicit the *de qi* sensation. In addition, each session includes a joint-specific point prescription tailored to up to four of the patient’s most painful joints, including knees, fingers, lumbar area, shoulders, hips, and wrists. If needed, to access joint-specific points that are not accessible in the supine position, needles may be inserted after the first set, at the proper depth and angle, eliciting a *de qi* sensation, and retained for 10 minutes. No electrical stimulation is used. The anatomic site selection may vary between visits depending on the patient’s current symptoms.

Stainless steel, single-use, sterile and disposable needles are used for the intervention and are inserted at traditional depths and angles. Clinicians are instructed to achieve a *de qi* sensation, in which patients experience a dull or achy feeling considered to be indicative of effective needling.[17] Needles are re-stimulated manually once during each session. The full body acupuncture needles used are 1 inch, 1.5 inches and 34-gauge or 3 inches and 30-gauge (manufactured by Tian Jin Haing Lin Sou Won Medical Instrument Co., Ltd; distributed by Mac Co., Roslyn Heights, New York, USA) and the auricular needles are 15mm and 38-gauge (Seirin-America, Inc., MA).

Sham Acupuncture Protocol—Number, duration, and frequency of the sessions in the sham acupuncture group are the same as for the true acupuncture group. Table 2 displays the sham acupuncture point protocol. The sham acupuncture point prescription was selected based on a previous cooperative group study testing acupuncture versus sham acupuncture for delayed nausea in pediatric patients undergoing highly emetogenic mixed-chemotherapy for solid tumors (Kara Kelly, personal communication, data not published) as well as our previous trials utilizing this sham protocol for the indication of AI-induced arthralgias.[8] The sham protocol consists of a core standardized prescription of minimally invasive, shallow needle insertion utilizing thin and short needles at non-acupuncture points. Joint specific sham point protocols are also based on the aforementioned criteria and are also within the proximity of the specified anatomic area. Preliminary results from our previous studies suggest that there is a difference between deep and localized needling for the joint pain commonly experienced by patients with AI-induced arthralgias. Moreover, we have demonstrated that our sham method did provide adequate blinding among patients.[8]

In each session, four standardized points are needled bilaterally and superficially using fine needles (*i.e.*, superficial acupuncture at non-meridian points). *De qi* and manual stimulation of the needles were avoided. The sham acupuncture protocol also includes joint-specific treatments and an auricular sham intervention based on the application of adhesives to non-acupuncture points on the ear. Sham acupuncture needles are Mac™ single-use, sterile, and disposable with plastic guide tube. The sham acupuncture needles are 0.5 inch 34-gauge (manufactured by Tian Jinhaing Lin Sou Won Medical Instrument Co., Ltd; distributed by Mac Co., Roslyn Heights, New York, USA). The auricular sham product used is Sakamura Magrain Ear Pellet, silver, with pellets removed (manufactured by Sakamura Lab & Co., Kyoto, Japan). The auricular adhesives are loosely attached and pressed to the sham points on the helix of the auricle, and removed at the end of the treatment.

Training Acupuncturists and Clinical Research Associates

Prior training of acupuncturists—True and sham acupuncture interventions are provided by licensed acupuncturists (at least 3000 hours) and medical doctor acupuncturists (at least 100 hours). At the time of study initiation, the acupuncturists were already on staff at the clinical sites, or were on staff at the community based clinics affiliated with the cancer center or academic medical center.

Human subjects training—All acupuncturists completed human subjects training per their institutional guidelines for conducting human subjects research.

Online training—Adobe Captivate 5 (www.adobe.com) was used to develop online training presentations for study acupuncturists that combine visual, verbal and video elements. These include an introductory module which covers general information about the study and two acupuncture-specific modules. An “Introduction to the S1200 study” site training module (10 minutes) includes information on the purpose of the study, information on SWOG study operations locations including the statistical center and biorepository, S1200 study sites, study design and objectives, basic eligibility criteria, blinding, assessments, patient confidentiality, basic adverse event reporting and contact information.

Two modules were developed to specifically train study acupuncturists. The first acupuncture module (15 minutes) covers data transfer and reporting methods, notification of patient registration and group assignment, documentation of patient visits, treatment frequency and timing, blinding, demeanor with study patients, clean needle technique (CNT) and true acupuncture points, materials and techniques including pictures and verbal descriptions of the anatomical locations of true body and auricular points used in the study. The second acupuncture module (10 minutes) covers sham acupuncture points, materials and techniques including pictures and verbal descriptions of the anatomical locations of the sham body and auricular points used, along with videos of the location and needling of each sham body point and methods for sham auricular points.

Each module ended with a short quiz covering information presented in the module. Upon successful completion of the quiz, the acupuncturist sends an email generated by Captivate to the coordinating clinical research associate (CRA) at Columbia University.

Training manuals—Written training manuals for acupuncturists were developed and distributed to each site, covering the same information as in the online training. Manuals are updated throughout the duration of the trial, as needed.

In-person acupuncturist training—At least one acupuncturist from the initial study institutions attended a 4-hour training session at the SWOG conference in San Francisco, CA in April 2012. The session included a study overview presentation for S1200 acupuncturists, CRAs and other S1200 staff and investigators in attendance. A CRA-specific presentation was made that included a question and answer period. During the last 2 ½ hours of the training, study acupuncturists were shown and practiced sham point locations, needling methods and techniques. Acupuncturists (JC, AJ) from the lead site, Columbia University, also conducted visits to study sites for additional training as needed. On-site visits last 4–6 hours depending on the number of acupuncturists at each site, and consist of reviewing the training manual, paperwork and procedures, and approximately 1 ½ hours of one-on-one training in sham and true treatments for each acupuncturist. Ongoing monthly teleconferences with study acupuncturists, CRA’s and investigators are also conducted to address questions and concerns of study personnel.

Quality assurance for acupuncturists—In order to maintain quality assurance for the acupuncturists performing the study procedure over the entire study period, methods for yearly quality assurance training of the study acupuncturists were devised. Quality assurance training includes 2 separate annual assessments. The first is a web-based quiz of multiple

choice questions that are related to the study protocol and procedures. The quiz is administered, data are collected and answers are discussed in an open fashion on a subsequent monthly follow-up teleconference. The quiz answers are also distributed to all study acupuncturists for their reference. The second training assessment is an actual practical demonstration of study procedures with regard to greeting and assessing the study patient, as well as acupoint location and needling technique for both the true and sham protocols respectively. The study acupuncturists are given the option to perform a live video based quality assurance session with the lead site's acupuncturist, or perform a recorded video assessment that is sent to the lead site's acupuncturist. An assessment tool using a 3-point scoring system (1=pass, 2=acceptable but needs follow up, 3=unacceptable and needs follow up) is used to assess the domains including greeting, point location accuracy, needle technique and any other pertinent issues to the protocol and procedures. Table 3 displays the domains assessed in the assessment tool. Acupuncturists scoring a 2 or 3 in any domain are given additional written, verbal or video-based trainings with the lead acupuncturist as needed.

Randomization and blinding of acupuncture status

Once a patient is enrolled in the trial, they are randomized by the SWOG statistical coordinating center in a 2:1:1 ratio to true acupuncture vs. sham acupuncture vs. waitlist control. If a patient is randomized to the true or sham acupuncture condition, the SWOG statistical coordinating center sends an email to the acupuncturists to notify them that a patient has been assigned. Next, the acupuncturist logs into the SWOG statistical coordinating center website to retrieve the assignment. The acupuncturist is the only member of the site study team that is unblinded to the sham and true acupuncture assignment.

To maintain blinding, the data on the true or sham point prescription administered at each visit will be entered into a separate locked database, which will only be accessible to the study acupuncturist(s) and an unblinded CRA at Columbia who does not have contact with patients.

Data Collection by Acupuncturists

In the S1200 trial, acupuncturists complete a SWOG case report form (CRF) for each treatment. CRFs were developed by the study team at Columbia University and include participant ID number, initials, date, acupuncturist name and institution. The treating acupuncturist checks boxes to indicate the study session number, the true or sham full body points treated, unilateral point administration, and the unilateral auricular points treated during the acupuncture session. For both true and sham treatments groups, additional treatment of up to four painful joints is indicated by check boxes. S1200 is using an intent-to-treat analysis. Acupuncturists indicate if study patients receive fewer acupuncture points than the full study protocol for any reason. Acupuncturists also assist in monitoring for protocol adverse events related to the procedures by checking whether the patient reported any bruising, bleeding, infection, needle shock or other reactions since the previous acupuncture session. Acupuncturists complete and submit each treatment form within 24 hours. To submit forms, acupuncturists scan the form to create an Adobe PDF file on a

secure, password-protected computer or fax the treatment form directly to the unblinded CRA at Columbia University. Acupuncturists log onto a SWOG secure file transfer (sFTP) site using a SWOG ID and password, from a pre-verified IP address. Once logged on to the sFTP site, the PDF file can be dragged and dropped into a site- and patient-specific folder, which is only accessible to acupuncturists at their institution, and an unblinded CRA at Columbia University, who collects and records treatment information.

Current status

S1200 was activated on March 27, 2012. As of February 16, 2015, a total of 141 patients have been enrolled at 11 clinical sites. There are currently 33 acupuncturists participating in the trial. Trial accrual is anticipated to close in October 2016.

Discussion

New robust methods were developed to train acupuncturists and staff to implement a large scale, multi-site randomized sham- and waitlist-controlled clinical trial testing the effects of a standardized acupuncture protocol on aromatase inhibitor-associated joint pain. The trial is currently underway. Novel training methods included online training modules, peer-training, and remote quality assurance monitoring. Trial results are anticipated in 2017.

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References

1. Baum M, Budzar AU, Cuzick J, et al. Anastrozole alone or in combination with tamoxifen versus tamoxifen alone for adjuvant treatment of postmenopausal women with early breast cancer: first results of the ATAC randomised trial. Lancet. Jun 22; 2002 359(9324):2131–2139. [PubMed: 12090977]
2. Thurlimann B, Keshaviah A, et al. Breast International Group 1–98 Collaborative G. A comparison of letrozole and tamoxifen in postmenopausal women with early breast cancer. N Engl J Med. Dec 29; 2005 353(26):2747–2757. [PubMed: 16382061]
3. Coombes RC, Hall E, Gibson LJ, et al. A randomized trial of exemestane after two to three years of tamoxifen therapy in postmenopausal women with primary breast cancer. N Engl J Med. Mar 11; 2004 350(11):1081–1092. [PubMed: 15014181]
4. Goss PE, Ingle JN, Martino S, et al. Randomized trial of letrozole following tamoxifen as extended adjuvant therapy in receptor-positive breast cancer: updated findings from NCIC CTG MA.17. J Natl Cancer Inst. Sep 7; 2005 97(17):1262–1271. [PubMed: 16145047]
5. Goss PE, Ingle JN, Martino S, et al. A randomized trial of letrozole in postmenopausal women after five years of tamoxifen therapy for early-stage breast cancer. N Engl J Med. Nov 6; 2003 349(19): 1793–1802. [PubMed: 14551341]
6. Howell A, Cuzick J, Baum M, et al. Results of the ATAC (Arimidex, Tamoxifen, Alone or in Combination) trial after completion of 5 years' adjuvant treatment for breast cancer. Lancet. Jan 1–7; 2005 365(9453):60–62. [PubMed: 15639680]

7. Crew KD, Capodice JL, Greenlee H, et al. Pilot study of acupuncture for the treatment of joint symptoms related to adjuvant aromatase inhibitor therapy in postmenopausal breast cancer patients. J Cancer Surviv. Dec; 2007 1(4):283–291. [PubMed: 18648963]
8. Crew KD, Capodice JL, Greenlee H, et al. Randomized, blinded, sham-controlled trial of acupuncture for the management of aromatase inhibitor-associated joint symptoms in women with early-stage breast cancer. J Clin Oncol. Mar 1; 2010 28(7):1154–1160. [PubMed: 20100963]
9. Cherkin DC, Sherman KJ, Hogeboom CJ, et al. Efficacy of acupuncture for chronic low back pain: protocol for a randomized controlled trial. Trials. 2008; 9:10. [PubMed: 18307808]
10. Cherkin DC, Sherman KJ, Avins AL, et al. A randomized trial comparing acupuncture, simulated acupuncture, and usual care for chronic low back pain. Arch Intern Med. May 11; 2009 169(9): 858–866. [PubMed: 19433697]
11. Brinkhaus B, Witt CM, Ortiz M, et al. Acupuncture in seasonal allergic rhinitis (ACUSAR)--design and protocol of a randomised controlled multi-centre trial. Forsch Komplementmed. Apr; 2010 17(2):95–102. [PubMed: 20484917]
12. Brinkhaus B, Witt CM, Jena S, et al. Physician and treatment characteristics in a randomised multicentre trial of acupuncture in patients with osteoarthritis of the knee. Complement Ther Med. Sep; 2007 15(3):180–189. [PubMed: 17709063]
13. Melchart D, Streng A, Hoppe A, et al. Acupuncture in patients with tension-type headache: randomised controlled trial. BMJ. Aug 13; 2005 331(7513):376–382. [PubMed: 16055451]
14. Witt CM, Jena S, Brinkhaus B, Liecker B, Wegscheider K, Willich SN. Acupuncture for patients with chronic neck pain. Pain. Nov; 2006 125(1–2):98–106. [PubMed: 16781068]
15. Li Y, Zheng H, Witt CM, et al. Acupuncture for migraine prophylaxis: a randomized controlled trial. CMAJ. Mar 6; 2012 184(4):401–410. [PubMed: 22231691]
16. MacPherson H, Altman DG, Hammerschlag R, et al. Revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT statement. J Evid Based Med. Aug; 2010 3(3):140–155. [PubMed: 21349059]
17. Hui KK, Nixon EE, Vangel MG, et al. Characterization of the “deqi” response in acupuncture. BMC Complement Altern Med. 2007; 7:33. [PubMed: 17973984]

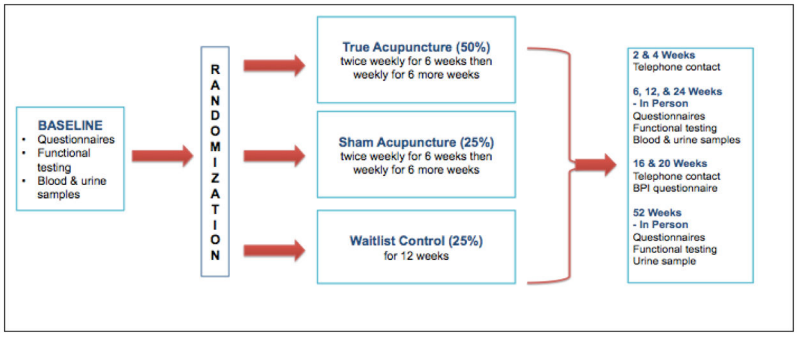

Figure 1.
Study Schema

Table 1

True Acupuncture Protocol

Full body acupuncture points

- SJ 5
- LI 4
- GB 41
- GB 34
- ST 41
- KD 3

Auricular acupuncture points

- Shen Men
- Kidney
- Liver
- Upper Lung
- Sympathetic

Joint-specific acupuncture point protocols

Shoulder

- LI 15
- SJ 14
- SI 10

Wrist

- SI 5
- SJ 4
- LI5

Fingers

- SI 3
- Ba Xie
- LI 3

Lumbar

- DU 3
- DU 8
- UB23

Hip

- GB 30
- GB 39

Knee

- SP 9
- SP 10
- St 34

Table 2

Sham Acupuncture Protocol

Full body acupuncture points

- Sham 1 - On the lateral side of the left forearm, near the elbow, 3 cun below the olecranon, 0.5 cun toward the anterior of the small intestine acupuncture meridian
- Sham 2 - On the lateral side of the right forearm, near the elbow, 3 cun below the olecranon, 0.5 cun toward the anterior of the small intestine acupuncture meridian
- Sham 3 - At the lower border of the medial condyle of the left tibia, 1 cun anterior and superior to *xi guan* (Liv 7) of the liver acupuncture meridian
- Sham 4 - At the lower border of the medial condyle of the right tibia, 1 cun anterior and superior to *xi guan* (Liv 7) point of the liver acupuncture meridian

Auricular acupuncture points

- A Sham 1 - On the helix of the auricle between the ear apex and helix point #1
- A Sham 2 - On the helix of the auricle between helix point #4 and #3
- A Sham 3 - On the helix of the auricle between helix point #5 and #6

Joint-specific acupuncture point protocols

- Shoulder - On the lateral side of the left or right upper arm, 5 cun below the anterior axillary fold, and 1 cun anterior to the Lung acupuncture meridian
- Fingers/Wrist - On the lateral side of the left and right forearm, near the elbow, 5 cun below the olecranon, 0.5 cun toward the anterior of the small intestine acupuncture meridian
- Lumbar - On the back at the level of thoracic vertebra 8, 5 cun from the center of the spine, 2 cun from the outer channel of the urinary bladder acupuncture meridian, needled bilaterally
- Hip - On the thigh, approximately 4 cun above the patella, 1 cun away from the anterior of the Gallbladder acupuncture meridian
- Knee - 2 cun above sham 3 or 4, respectively

Table 3

Annual live or video quality assessment domains

Greeting
• Neutral demeanor
• Greeting for standard first visit
• Greeting for standard follow-up visit
• Inquiry about existing joint pain
Set up
• Clean field technique
• Hand washing
• Point swabbing
• Immediate isolation of used needles
Point location
• Use of bony landmarks
• Use of local anatomy
• Cun measurement
Needles
• Selection of proper needle type
• Selection of proper length
Technique
• Insertion
• Proper technique with tube
• Proper auricular technique
• Proper technique with sham needle
• Stimulation
• Obtaining *de qi*
• Even technique