

A Qualitative Analysis of Adolescents' Experiences of Active and Sham Japanese-Style Acupuncture Protocols Administered in a Clinical Trial

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Abstract

Introduction: Acupuncture is a complex holistic intervention in which patient–practitioner relationships and healing changes occur in interactive, iterative ways. Qualitative research is one way to capture such complexity. This study sought to understand better the experiences of adolescents involved in acupuncture treatment. **Materials and methods:** We included a qualitative substudy as part of a pilot randomized sham-controlled study of the use of Japanese acupuncture to treat chronic pelvic pain in adolescent girls. Seven (7) interviews were attained. Themes were double-coded and analyzed using qualitative analysis software. **Results:** Regardless of treatment arm, all subjects reported positive study-related changes, often attributed to positive qualities of the patient–practitioner relationship. Participants in both the sham and verum acupuncture treatment arms reported in the narratives that they were unsure of their study assignment. In contrast, the study's close-ended success of blinding question suggests that some participants were sure of their treatment allocation. **Conclusions:** As we continue to study acupuncture using sham controls, we need a better understanding of the possible affects of sham treatments on both treatment outcomes and success of blinding. Qualitative research is one-way to explore subtle emergent changes in participants' experiences.

Introduction

Adolescent chronic pelvic pain (CPP) is a common condition accounting for 10% of outpatient gynecology visits in this population.¹ CPP is most commonly defined as recurrent or persistent pain in the lower abdominal region that lasts for 6 months or longer.² A complex constellation of symptoms associated with significant morbidity and negative influence to quality of life for both adolescents^{3,4} and adults,⁵ CPP is of particular potential impact for adolescents, as health problems early in life can influence later development.⁶ Like other complex ailments, CPP can have multiple etiologies, making diagnosis and treatment challenging. For example, some cases of CPP are diagnosed as being caused by endometriosis leading to a treatment course targeted at treating the endometriosis. It is believed that 25%–38% of adolescents with chronic pelvic pain have endometriosis.^{7–9} Yet, even when a firm diagnosis of endometriosis is found, current treatments for this physical pathology are often ineffective in relieving CPP symptoms¹⁰ and many carry negative side-effects.¹¹

Acupuncture is frequently utilized for conditions associated with pain, including those related to gynecologic issues.^{12–18} Pediatric and adolescent use of complementary and alternative medicine (CAM) practices such as acupuncture is increasing^{19–21}; however, few studies have evaluated acupuncture for adolescents with gynecologic conditions with respect to feasibility, patient satisfaction, and patient acceptance. Moreover, while Japanese-style acupuncture (JA) has been shown to be effective in the treatment of pain,²² we are not aware of any studies that have evaluated the efficacy and safety of this style of acupuncture in an adolescent population. JA was chosen for use in this study because we evaluated a vulnerable adolescent population. JA, which is commonly believed to have developed in Japan from Chinese influence in the early fifth century,²³ is generally thought to be less invasive than other forms of acupuncture. For example, compared to the acupuncture practiced as part of Traditional Chinese Medicine (TCM), JA uses thinner needles, more shallow needle insertions, and less-vigorous needle stimulation.²⁴ We also chose JA because, in comparison to TCM, JA is understudied in the West.²⁵ While there is

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some published work supporting high tolerance for acupuncture in pediatric populations,²⁰ to our knowledge, no studies have utilized a pediatric or adolescent sample to explore the efficacy and experience of JA.

Acupuncture is a complex holistic intervention, in which patient-practitioner relationships and healing changes occur in interactive, iterative ways. Qualitative techniques offer one way to capture this complexity,²⁶ enriching our scientific knowledge beyond what can be gained quantitatively.²⁷ Patients frequently report that they enjoy the experience of acupuncture treatments and that these holistic CAM modalities offer nonspecific positive effects that may be lacking in conventional allopathic treatments. Qualitative research, which collects data on the lived experiences of participants, is a useful tool for exploring such experiences.

We conducted a pilot, randomized, sham-controlled study to evaluate the potential application of JA for treating endometriosis-related chronic pelvic pain in adolescents.²⁸ As part of this study, we conducted 7 qualitative interviews to explore the participants' experience of acupuncture and their illnesses. The qualitative substudy was added to capture the complexity of illness and treatment experiences. Findings from this work may help in the design of future studies as well as improving our understanding of acupuncture and the illness experience of CPP. Acupuncture studies using adolescent samples are rare, and to design better interventions, we need to know not only if this population can tolerate acupuncture but also how this population experiences and understands the treatments. In this paper, we summarize the results of this qualitative substudy and discuss the relevance of the results to the feasibility and design of future more definitive studies.

Methods

Design of parent clinical trial

The parent study in which the qualitative assessments took place was a prospective, randomized, sham-controlled trial with blinding of patients and outcome assessors.²⁸ A total of 18 study participants were identified and recruited primarily through the Division of Gynecology of Children's Hospital, Boston, MA. Eligibility criteria for study participants included: age 13–22 years old; diagnosis of stage I, II, or III endometriosis determined by laparoscopic surgery within past 5 years; persisting pelvic pain with an intensity between 2 and 8 on a 10-point numerical scale; postmenarchal; intact uterus and at least one ovary; a candidate for or already using combination hormonal therapy (oral contraceptive pill, contraceptive patch, or contraceptive vaginal ring); no prior experience with acupuncture; and living within 2 hours of the Boston metropolitan area. Study candidates were excluded from consideration if they were pregnant or lactating; had histories of drug or alcohol abuse; had used a gonadotropin-releasing hormone (GnRH) analogue such as Lupron (TAP Pharmaceutical Products, Inc., Los Angeles, CA) within the 6 months prior to their participation in the study; or had coexisting disabling physical or psychiatric conditions that the study physician believed might interfere with participation in the study.

Participants assigned to either the active or invasive sham groups underwent a total of 16 acupuncture treatments; 2 per week for 8 consecutive weeks. Treatments were admin-

istered by licensed acupuncturists with formal training in JA. Treatments were conducted either in acupuncturists' private offices or in the homes of study participants for those who opted for home treatments.

Our main study outcome measure was change in pelvic pain not associated with menses and sexual activity; these were assessed 8 weeks after treatment. Secondary outcomes included a range of psychosocial instrumentation including quality of life testing. We also assessed patients' expectations regarding the benefits of acupuncture treatment and assessed success of blinding. Further details regarding the study design and quantitative results are presented elsewhere.²⁸ A few of the findings from the quantitative measures from the parent study are reported per subject in this paper. The first is the Endometriosis Health Profile-30, a reliable and valid measure of endometriosis-related quality of life.^{29–31} Higher scores indicate worse quality of life. The second is degree of pelvic pain not associated with menses and sexual activity. The second test is based on the pain intensity question contained in the Endometriosis Symptom Severity Scale.³² Participants were asked to rate their pain using a numerical analog scale with 0 representing no pain and 10 representing the worst pain imaginable. Blinding was assessed by asking the participants to indicate the treatment group to which they believed they were assigned by circling the applicable statement: (1) "I believe I am in the active acupuncture group"; (2) "I believe I am in the inactive, sham acupuncture group"; (3) "I am unsure what group I am in." This instrument has been used in other acupuncture trials.^{33,34}

Design of qualitative substudy

We conducted semistructured interviews on a sample of 7 participants. The target sample of the parent study was 40, and assignment to the qualitative group was initially by random allocation. Yet due to limitations in recruitment to the parent study, 1 year into recruitment, all entering participants in the parent trial were invited to participate in the qualitative substudy. All of the participants in the parent trial who were offered participation in the qualitative substudy agreed to participate. No further selection procedure was used. Topics covered in the interview using direct questions included: illness experience, illness model, experience with acupuncture, relationship with acupuncturist, social support, and experience with the study. All interviews took place after all treatments were completed and primary endpoints were assessed but before participants were unblinded.

The interviewer (L.C.) introduced herself to each participant as a member of the study staff who was interested in learning more about the participant's experiences with CPP, acupuncture, and the study more generally. The interview agenda covered the participant's experiences with CPP, including allopathic and CAM treatment history, model of illness, and the participant's beliefs about how the condition might affect her ability to function at work, school, and in social relationships. Each participant was also asked to describe her acupuncture experience and her relationship with the acupuncturist. Finally, each participant was asked what course she expected her CPP to take. Interviewers were careful to emphasize patient anonymity and confidentiality. All of the participants were naïve to acupuncture.

The interviews were transcribed verbatim and the text was analyzed using the Atlas ti program (Scientific Software Development, Berlin, Germany) and directed by a grounded theory approach.³⁵ The transcripts were double-coded independently by 2 of the authors (L.C. and M.Q.). The coders remained blinded to study treatment arm until after the final codes had been determined. Any disagreements in coding were discussed. Coding consisted of searching for sought themes and emergent themes in each transcript as well as condensing responses to each topic across the sample. After the emergent codes were determined, we broke the sample into patients who received real and those who received sham acupuncture to compare for differences by type of treatment offered.

Results

Due to the nonrandom nature of the sampling, offering frequencies of the qualitative reporting of particular themes made little sense. Instead, terms such as "all," "most," "a few," and "one" were used following the recommendations of Price et al.³⁶ In this analysis, "most" is defined as a majority of respondents. "Few" is defined as more than 2 respondents but less than half of the sample. In the qualitative narratives, the sham and verum acupuncture groups reported similarly across the sought themes and emergent codes and qualitatively reported efficacy of treatment. When questioned during the interviews about study arm allocation, in the narratives, all of the subjects reported that they were unsure if they had received real or verum acupuncture. All of the participants reported confusion and frustration in living with CPP, with serious effects on quality of life. Although many patients expected acupuncture to be uncomfortable, all reported positive acupuncture experiences even if the primary symptom of chronic pelvic pain was not reduced. A key theme that emerged is the psychosocial and therapeutic importance of a positive patient-practitioner relationship. Most participants reported a desire to continue acupuncture treatments, only noting the hindrance of financial cost. The major themes found are presented below with selected narrative examples. To describe the sample further, Table 1 offers selected quantitative descriptors of the qualitative substudy sample.

Experience of illness

All of the participants spoke of the difficulty of managing CPP and frustration at the lack of effective allopathic treatments. Only 1 of the 7 interviews reported pain reduction

associated with the laparoscopic procedure. All of the adolescents reported frustration and a lack of allopathic medical explanation for, or understanding of, their pain. Even after being given the diagnosis of endometriosis and experiencing the endoscopy, many of the adolescents still reported a lack of medical explanation and continued pain.

Participant: I finished college in August of last year, and then September and October I started to feel a lot of pain, so I went just a regular gynecologist where I live, and they did all of this stuff and had no idea what was going on, which was irritating. . .and she did an ultrasound, she did lots of blood tests and stuff like that, and everything seemed to be fine, but I was feeling worse and worse, so she was like "I am at a loss, I don't know what to do with you, you should go to the Children's Hospital" . . .because I have a metabolism doctor there. So I went to see my metabolism doctor, she verified it was unrelated to muscles, and she suggested that I see (the pediatric surgeon) at the Children's Hospital—so I went to see him in January, and he scheduled the surgery for February.

Interviewer: Did it (the surgery) help?

Participant: At first, I felt immediately a lot better, but I am not sure if that was due to the fact that I just finished the surgery and after I recovered from the surgery then I was feeling better just in general, because he lasered off all the . . .whatever. . .but recently I had been feeling a lot worse again. . .and I called the surgeon, and we decided I am going to have to try a new pill, higher dose. [Participant 113, age 22, active acupuncture]

Many of the adolescents reported confusion regarding the cause of their disease and how it might be effectively treated.

Um, well my mom told me it was maybe stress-related, I don't really know if it is stress, I mean it hurts sometimes when I am very stressed and I have a lot of things going on and I can't handle it, then when I can't deal with it anymore then occasionally it will affect me and make it even worse, but I don't really feel the pain during most of my stress, it is just here and there usually. I don't really know why I have it. . .well, my mom and my aunt have it, so maybe I just developed it, but the other tests that they are doing says that it says it could be more, because it is not just endo pain, which I had surgery to correct, but it still hurts, so they are doing re-

TABLE 1. SELECTED QUANTITATIVE DESCRIPTORS OF THE QUALITATIVE SUBSTUDY SAMPLE^a

Participant	Age	Treatment group	Baseline pain (0–10)	Pain at 8 wk (0–10)	Baseline QOL (0–100)	QOL at 8 wk (0–100)	Belief of treatment group at 8 wk
103	15	Sham	8	5	27	27	Unsure
104	16	Verum	6	5	22	8	Active
110	20	Sham	8	2	20	44	Active
111	16	Sham	8	6	56	48	Inactive
113	22	Verum	8	4	29	30	Active
118	14	Verum	10	0	40	3	Active

^aHigher pain scores indicate more pain and higher quality-of-life scores indicate worse quality of life.

search on more, they don't think that it is just endometriosis, and I think it is probably more than that. [Participant 118, age 14, active acupuncture].

All of the adolescents also spoke of multiple social effects of illness, such as loss of time at school and work. This was often compounded with fears surrounding possible negative effects of their allopathic treatments.

Participant: In terms of work, I mostly went, but I was feeling a lot of pain when I came back; definitely [I lost] parts of my senior year from it. I think that the birth control had an effect on just my hormones in general, and, like I was also stressed out senior year, and that in combination with hormones that just wasn't good, I was a wreck.

Interviewer: You say "wreck"; what does that mean?

Participant: I don't know, just really stressed out, I don't know, I think that I got depressed on the type of birth control pill that I was on, so probably from that, I was really upset a lot and so until I found the one that I am on right now, I was really upset—it didn't really work too well, but I didn't want to take Lupron, it just kind of scared me, the side effects to it. (Participant 110, age 20, sham acupuncture)

Expectations of acupuncture

None of the adolescents had experience with acupuncture previous to participation in this study, but 2 had used other types of CAM before including yoga, herbs, and Reiki. All the adolescents thought that acupuncture would be uncomfortable before they tried it, reporting fears of needles and needling discomfort; some indicated too that these fears were normative in their peer group.

Interviewer: What kind of reaction do you get from your friends?

Participant: Like, "oh my gosh, does it [acupuncture] hurt, what does it feel like, does it work," that is what they all say. [Participant 112, age 20, active acupuncture]

All of the adolescents reported family support for their use of acupuncture. The participants portrayed themselves and their families as frustrated by the lack of success of previous treatments. They were willing to try options to gain relief.

Well, I have tried some different things to get rid of this, and my mom and I figured why not try it, just to see what it can do and if it can help, great, but if it can't, we tried. It just seems like a good thing to try, and plus acupuncture—I never knew anything about it, so it was interesting to learn about it too. [Participant 111, age 16, sham acupuncture]

All of the adolescents had similar stories of trying multiple types of treatments before joining the study. The most frequently cited reason for not trying acupuncture in particular was expense, as acupuncture is frequently not covered by medical insurance.

Interviewer: Why did you decide to join the study?

Participant: I forget who even brought it to my attention, I think when I went to [the treating physician, he]

kind of asked me, he originally said to do acupuncture, and it was too much money to do, and I was just kind of like, "whatever," and then I heard about it and me and my mom were like: "Let's try it." [Participant 112, age 20, active acupuncture]

Experience of acupuncture

All of the adolescents reported exclusively positive experiences with the acupuncture treatments, even if the treatment did not improve their pelvic pain. Acupuncture was "fun," not serious or stressful. One participant reported in answer to the question "What was your acupuncture experience like?":

It was really good, I am not really sure how well it did with the endometriosis, I am not really sure it took away that much pain, but when I went, it was a major stress reliever and really relaxing, and the heat on my back. . . the stones, those felt really good, especially after it, it really helped. I really liked it, but I am not sure how well it worked, like, I couldn't see that much of an improvement, like, I saw somewhat [an improvement], but not complete[ly]. It is really hard to tell, like I really enjoyed it but it didn't get rid of the pain I wouldn't say. [Participant 110, age 20, sham acupuncture]

All of the participants reported that the actual treatments were relaxing, and most patients said that they fell asleep during treatments. Some patients reported improved pain and all reported improved mood or reduced feelings of stress.

Um, I think my frustration and my feelings and emotions were a lot calmer [with treatment]. . . . With my friends, before [starting treatments] when I got frustrated I couldn't handle jokes. . . . I was very serious, I didn't want to laugh about certain stuff and I was strict and not fun to be around, and I am a lot goofier now, and sort of loose, and I don't really get frustrated with things. I can handle stress much better. [Participant 118, age 14, active acupuncture]

Reports about the relationship with practitioner

All the adolescents reported positive patient-practitioner relationships. Specific positive qualities of the relationships included practitioners' expressions of empathy, practitioners finally offering explanations or models for understanding the problems, positive practitioners' expectations for treatment, and patients feeling empowered by the practitioners to engage in positive health behaviors. Many of the adolescents reported that the acupuncturists treated the patients as individuals and that the interactions were pleasant and unrushed. This was frequently presented in contrast to their previous experiences with allopathic medicine as outlined in the "Experience of Illness" section earlier.

She's really nice. She's very, like, relaxed and calm, and expressive. [Participant 103, age 15, sham acupuncture]

I really liked my acupuncturist, I really liked going, it is really relaxing, I usually fall asleep. [Participant 110, age 20, sham acupuncture]

She just explained that she treated a lot of people that had the same or had maybe a feeling of what I felt. . .

and that it was okay to talk about what was bothering me, whether it was emotionally or physically, and then she said that she would try to figure it out—not to try and take little interviews or questionnaires [about] my pain, like not to keep pestering me about what it was each time I arrived, but she was just very calm, she didn't push anything. [Participant 118, age 24, active acupuncture]

It [the acupuncture] was really good. She was really supportive. I considered her like a friend. I could talk to her. It was good to talk to her and she was really helpful, telling me what parts of my body weren't doing too well, maybe stuff I could do. . . . She was really good through the whole thing and I really wanted to continue with her after if I could, so I am thinking about still going. [Participant 110, age 20, sham acupuncture].

Expectations of the future

When asked what they believed the progression of their illnesses would be, the adolescents all expressed fear of continued pain and pain management. The adolescents reported direct fear of pain as well as of the side-effects of medical pain management and subsequent effects on social functioning at work and school. A few of the adolescents also mentioned concerns that their fertility would be affected by their illnesses. One participant said:

Interviewer: Okay. . . Do you expect the illness to continue?

Participant: I hope not! But if I have it already at this age it could come back. . . you know.

Interviewer: Is there anything that worries you most about it?

Participant: Well, it can cause problems when you have kids, and I want to have children. [Participant 104, age 16, active acupuncture]

Others clearly reported a positive expectation with continuing acupuncture treatment. One patient said:

Interviewer: How do you expect your chronic pelvic pain to go in the future?

Participant: I don't know, hopefully it stays as it is, with the medicine I am on it is not that bad. If I have surgery every 2 years that also helps it, so hopefully not bad.

Interviewer: Would you ever want to go get acupuncture again?

Participant: Yes, I want to; hopefully I will get money to do that. [Participant 112, age 20, active acupuncture]

Conclusions

While there are multiple published narrative analyses of women with chronic pelvic pain^{36,37} and of adult experience of acupuncture,^{38–40} to our knowledge this study is unique in that it is the first to focus on adolescents' experiences with acupuncture treatment. One of the aims of the parent study was to determine the feasibility of conducting an acupuncture trial in this young population. Specifically, we wished to determine if the JA treatments administered in the context of a trial would be well-received by this population. Other work in the same population has found acupuncture

to be well-tolerated and enjoyed,⁴¹ a finding that is true of reports of adolescents' experiences of acupuncture use more generally.^{19,20} The qualitative component of this study found that our participants not only tolerate acupuncture well, they enjoy it and receive health benefits. All of the adolescents who participated in the interviews reported decreases in stress or improvements in mood, suggesting that this type of acupuncture has health benefits beyond pain relief. Additionally, the adolescents reported the main reason for not trying acupuncture previously was cost, not fear, suggesting that this population would be open to trying acupuncture treatment if it were more readily financially accessible.

Many participants pointed out the therapeutic benefits of the patient–practitioner relationship found in traditional acupuncture. Our results in an adolescent sample mirror results found in adult populations. Patients value positive expectations from practitioners. Being offered a diagnosis followed by a clear treatment path was validating for each of these patients.³⁶ An explanation of the problem offers participants confidence and trust,²⁶ especially for a condition like CPP, which may not have a discernable physical cause and therefore may be difficult to treat. Other qualitative work in adult populations with CPP has found that patients can feel invalidated by conventional medicine practitioners.⁴²

Many adolescents in our sample reported that the acupuncturists treated the patients as individuals and that the interactions were pleasant and unrushed. Furthermore, such interactions can give patients feelings of empowerment to improve their own self-care.²⁶ Patterson found that the Chinese medicine model offered to the patients can assist in positive changes in self-concept,³⁹ strength, energy, and social identity⁴⁰ and can help patients develop a holistic understanding of health problems, which can assist in positive outcomes and health behaviors. Indeed, such interactions can help patients become more self-reliant.²⁶

Our young participants reported valuing the nonthreatening practitioner relationships, which confirms other work in adult populations in which patients report valuing egalitarian patient–practitioner relationships.²⁶ Nonthreatening relationships may be even more important in a vulnerable adolescent population. Many of our participants reported that the interactions themselves were therapeutic, another result found in adult samples. Patterson and Britten²⁶ found that some patients see communication with their practitioners as part of therapy or as therapeutic. Patterson and Britten found that patients who felt communication and empathy in their relationships with their practitioners reported improvements in symptoms, while those patients who did not report these qualities did not report improvements. This suggests that when participants seek a therapeutic relationship and do not experience them, the patients' medical outcomes may be consequently affected negatively.²⁶

Researchers such as Grace support the idea that CPP is a holistic syndrome and should be treated holistically using an integrative model of care.^{43,44} The complexity of such interventions necessitates more complex methods of evaluation.⁴⁵ The use of qualitative methodologies is one way to capture the complexity of acupuncture.⁴⁶ Trials that focus on the effects of needling alone in ignorance of other aspects of the treatment process may alter and affect treatment outcomes,²⁶ and miss aspects of the treatment, such as the patient–practitioner interaction, that appear to be active components of healing.²⁶ Such qualitative information can be

useful in the design of future studies and enable a better understanding of what aspects of the acupuncture interaction are effective and how.

As we continue to study acupuncture, using sham controls, a better understanding of the ways in which sham and real treatment experiences differ and do not differ is necessary. Qualitative research on participant experience is an important part of such an investigation. In this study, all of the adolescents, when asked what study group they believed they were in, reported in the narratives that they were unsure if they had received real or sham treatment. Yet if the reader were only to consider the close-ended results in Table 1, it would appear that most of the adolescents were sure of their study-arm placement. Further analyses of the qualitative data will consider why the adolescents had doubts in their study-arm allocation and which parts of the intervention or study may have worked as cues toward unblinding.

In planning future studies in this area, it is useful to consider the qualitative results in light of the results offered in Table 1. The qualitative results indicate that regardless of study arm allocation, all of the participants reported positive changes in mood or stress. These positive changes were often attributed to the rich patient-practitioner relationship. These positive changes occurred even in those cases in which patients did not record reduced pain or improved quality of life on the quantitative instrumentation. Even the patients who did not believe that they were receiving real acupuncture reported benefits. This suggests that for some outcomes, both the sham and active arms are in some ways indistinguishable and may be effective in unique or similar ways.

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