



Original research article

# Auricular acupuncture as an adjunct for pain management during first trimester abortion: a randomized, double-blinded, three arm trial<sup>☆,☆☆</sup>



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## ABSTRACT

**Objectives:** To assess pain-management using auricular acupuncture as an adjunct to ibuprofen and paracervical block during first trimester uterine aspiration, and to assess auricular acupuncture's effect on anxiety.

**Study design:** This randomized, double-blinded, three-arm trial enrolled women undergoing uterine aspiration for spontaneous or induced abortion. Study participants were randomized 1:1:1 to receive auricular acupuncture, placebo, or usual care alone. Participants in all groups received ibuprofen and paracervical block (usual care). The main outcome was maximum pain reported at the end of the procedure measured using a Visual Analog Scale; we compared those receiving auricular acupuncture to those receiving usual care alone. We also compared auricular acupuncture to placebo and placebo to usual care alone. Finally, we compared the maximum anxiety scores between participants randomized to auricular acupuncture, placebo, and usual care alone.

**Results:** We randomized 153 women over 9 months, and analyzed 52 participants in the auricular acupuncture group, 49 in the placebo group, and 49 in the usual care group. The groups had similar baseline characteristics. After uterine aspiration, participants reported median maximum pain scores as follows: auricular acupuncture 39.5 (interquartile range (IQR) 11, 64.5), placebo 70.0 (IQR 40.5, 84), and usual care alone 71.0 (IQR 32, 91.5) ( $p < 0.01$ ). In pairwise comparisons, the median maximum pain score after auricular acupuncture was lower than placebo and usual-care groups ( $p < 0.01$  for both). Post-procedure median anxiety scores were 11.5, 31.0 and 44.0, respectively ( $p = .01$ ).

**Conclusions:** Women undergoing first trimester uterine aspiration assigned to auricular acupuncture reported substantially less pain and anxiety than women assigned to placebo or usual care.

**Implications:** Auricular acupuncture may be a useful adjunct to ibuprofen and paracervical block during first trimester uterine aspiration. This approach to managing pain and anxiety could avoid the operational complexities and expenses of sedation and opioid use.

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## 1. Introduction

Of the estimated 900,000 abortions performed in the United States in 2014, 90% were 1st trimester abortions [1]. Most aspiration abortions are performed in an outpatient setting with a paracervical block and nonsteroidal anti-inflammatory drug (NSAID) as the only

analgesics [2], but patients receiving these interventions still experience moderate pain [3–5].

Moderate sedation and general anesthesia decrease pain, compared to paracervical block and NSAIDs [5], but limited availability of these medications and personnel to administer them, as well as higher costs, risks, side effects, and delayed recovery time hinder their use [2]. Thus, pain control during first trimester abortions requires further research [6].

Pharmacologic and non-pharmacologic adjuncts to local anesthesia might decrease pain during aspiration procedures. Premedication with non-steroidal anti-inflammatory drugs (NSAID) is well established to improve pain control, but lorazepam, hydrocodone, acetaminophen, and oral midazolam administered prior to or during the procedure do not effectively mitigate or reduce pain [5,7–9]. Renner [5] found that hypnosis and relaxation exercises did not change reported procedural

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pain. One study found music was associated with less reported pain during abortion [10], but two trials did not reproduce this result [11,12].

Offering a range of adjuncts to local anesthesia had little effect on abortion-associated pain [13]. Thus, pain during first trimester abortions remains sub-optimally managed.

Acupuncture has the potential to complement local anesthesia by providing additional and synergistic analgesic and anxiolytic effects. Traditional Chinese medicine has located over 360 acupuncture points throughout the body. Pressure, needling or electricity can stimulate these acupoints [14], and using acupuncture might attenuate the perception of painful stimuli and anxiety. Peripheral stimulation of acupoints mobilizes central neuropeptides involved in the pathway of anxiety and stress. Acupuncture also activates opioid receptors, decreases COX-2 activity, and decreases inflammation, thereby inducing analgesia [15]. While acupuncture effects on abortion pain have not been studied, dysmenorrhea may be a related type of pain. A meta-analysis evaluated randomized controlled trials of acupuncture for dysmenorrhea relief and found that acupuncture was more effective than NSAIDs alone [16]. A 2016 Cochrane review also reported some evidence of acupuncture benefiting dysmenorrhea; however, the quality of evidence was low [17].

Auriculotherapy consists of stimulating designated acupoints on the external ear with needles, pressure, laser, or electrical stimulation to alleviate pain in other parts of the body [18]. Some points correspond to specific internal organs to induce analgesia, while other auricular acupoints decrease anxiety, and modulate pain perception and nausea [15,19]. A meta-analysis assessed 13 auriculotherapy pain management randomized trials that included a wide range of diagnoses (total  $N=806$ ) [20]. Most of the included studies treated chronic pain or non-gynecological post-operative pain; one study treated dysmenorrhea. The overall effect estimate supported substantial pain reduction, but the studies exhibited heterogeneity ( $I^2 = 95\%$ ), and in several studies the patient or the assessor was not blinded.

Auriculotherapy to treat pain uses pre-specified anatomic areas in the ear corresponding to body morphology. Most likely the battlefield acupuncture methodology, consisting of five auricular acupuncture points, favors processing and modulation of pain in the Central Nervous System involving the hypothalamus, thalamus, cingulate gyrus and cerebral cortex structures. We hypothesized that auricular acupuncture, using the Gold Protocol (see Appendix A), as an adjunct to a paracervical block and NSAIDs would minimize pain (and anxiety) compared to pain in women receiving paracervical block and NSAIDs alone during first trimester uterine aspiration.

## 2. Methods

This randomized, parallel-group, double-blinded, three-arm trial took place at a single abortion practice at Columbia University Irving Medical Center (CUIMC). The CUIMC Institutional Review Board (IRB) approved the study protocol and the study is registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT03391986). A single-arm pilot study, conducted in 2015 with 37 patients in the same setting assessed feasibility, workflow, and acceptability, and gave us experience using the Gold protocol prior to this randomized controlled study.

Eligible women were age 18 and older, English- or Spanish-speaking, had pregnancies less than or equal to 13 0/7 weeks gestation, were seeking first trimester uterine aspiration, and were willing to be randomized to receive auricular acupuncture, placebo, or usual care. Exclusion criteria included congenital anomalies of the ear, and allergies or contraindications to adhesives, ibuprofen, or lidocaine.

After approval from the attending physician, as our IRB required, a bilingual research assistant approached women after clinic registration, explained the study, and obtained written consent. Enrollment occurred in a private waiting room area immediately following registration so that clinic flow would have minimal interruption and participation in the study would not prolong participant visit time.

At enrollment, we collected demographic information, pregnancy history, and acupuncture history (ever/never). Participants completed 100-mm visual analog scales (VAS) to report baseline pain and anxiety level (0-mm = no pain/anxiety, 100-mm = worst pain/anxiety) [21]. VAS as an anxiety scale measure is correlated with measures from Spielberger's State Trait Anxiety Inventory (STAI) [22]. Participants entered their baseline information and VAS scores into a pre-programmed electronic tablet from which all information was transmitted directly into the study REDCap database.

After completing enrollment activities, participants continued with their usual clinical care, undergoing a pelvic examination, an ultrasound for gestational dating, and signing the procedure consent with the physician conducting the procedure. After the procedure consent was signed, the interventionist opened a sequentially numbered, sealed, opaque envelope containing the treatment group assignment without disclosing the assignment to the participant, research staff, or procedure staff. The three groups were: auricular acupuncture plus usual care, placebo plus usual care, or usual care alone. Study staff not involved in participant recruitment determined the 1:1:1 allocation in blocks of 6 using a random number table.

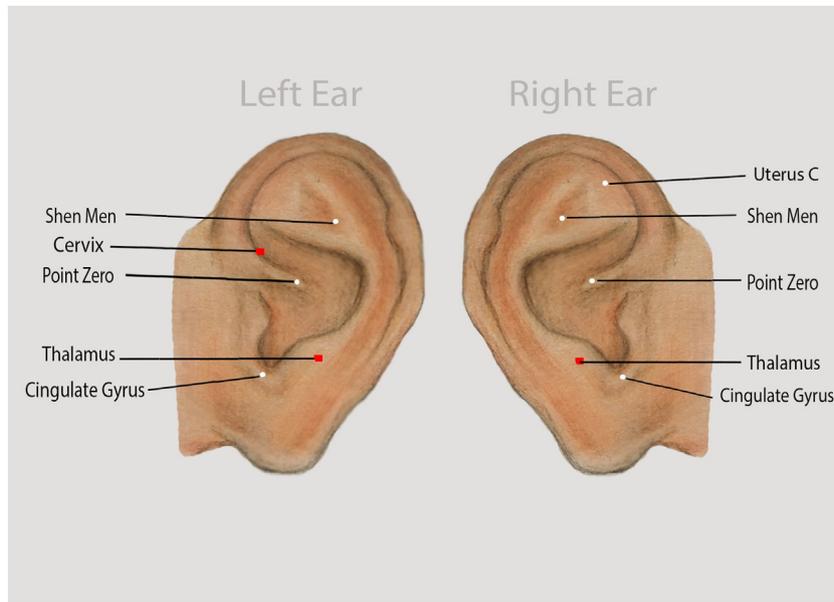
The interventionist followed a script to describe the intervention to participants randomized to receive auricular acupuncture or placebo. To maintain blinding, the interventionist script noted (correctly) that the needles may not be felt [23]. After cleaning both ears with alcohol, the interventionist placed Pyonex™ press needles 0.2 mm in diameter x 1.2 mm in length on a 12-mm adhesive base (Seirin Corp. Shizuoka, Japan). The interventionist placed the needles bilaterally, out of the view of the participant, using the Gold protocol acupoints [*cingulate gyrus, thalamus, Point Zero, Shen Men, Cervix (only left ear), Uterus C (only right ear)*]. An image of left and right ears demonstrates these points (Fig. 1).

For the placebo group participants, after similarly preparing both ears, the interventionist placed three to four 12-mm adhesives, out of the view of the participant, onto flat surfaces of each ear. The intervention required about 3–5 min and the interventionist spent approximately the same amount of time with both acupuncture and control-group participants. The interventionist then placed a surgical cap to cover the ears of participants in all three groups, and exited the procedure room. Two individuals performed all interventions: a licensed acupuncturist (LM) or an obstetrician-gynecologist (CN). Abortion providers were not present during the intervention, and thus, they remained blinded to group assignments. We maintained participant blinding in the acupuncture and placebo groups, although participants randomized to the 'usual care' arm of the study were aware of their assignment.

All participants underwent uterine aspiration by an attending gynecologist, family planning fellow, or gynecology resident. All patients received ibuprofen 800 mg orally about an hour before the procedure, and received a paracervical block with lidocaine 1% 20 mL immediately before the procedure. Uterine aspiration was performed at gestational ages less than or equal to 13 0/7 weeks.

Immediately following procedure completion, defined as speculum removal, the interventionist returned to ask the participant to use the tablet to record her maximum pain and anxiety scores using the same 100-mm VAS as at baseline. Participants responded to satisfaction questions with a Likert scale ranging from 1 = very dissatisfied to 5 = very satisfied and participants also reported which treatment they believed they had received. After data collection, the interventionist removed all Pyonex™ needles or placebo adhesives. Participants received \$25 for participation in the study.

The primary study objective was to evaluate auricular acupuncture effectiveness as an adjunct to ibuprofen and paracervical block for pain control during first trimester uterine aspiration. We compared the maximum pain score, measured by VAS, between women randomized to receive auricular acupuncture plus usual care and women randomized to usual care alone. We also compared maximum pain



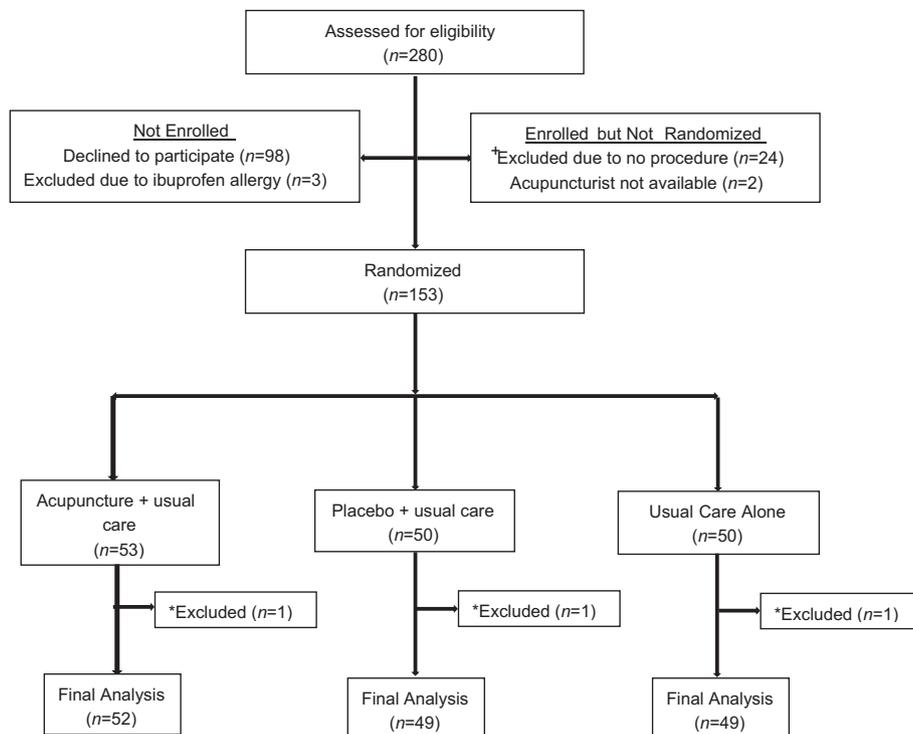
**Fig. 1.** Acupoints stimulated during this study of first-trimester aspiration abortion. White dots represent visible points on the outer ear surface and red squares represent points on the inner ear surface. Each participant underwent stimulation of all 10 points.

scores between auricular acupuncture versus placebo, and placebo versus usual care. Finally, we compared maximum anxiety scores with the same group comparisons: auricular acupuncture versus usual care, auricular acupuncture versus placebo, and placebo versus usual care.

We sought to identify a between-group difference in maximum pain score that would be clinically relevant: at least 15-mm on a 100-mm VAS [21]. Guerrero et al [11], evaluated music as an adjunct to a paracervical block that also used lidocaine 1% 20 mL during first trimester surgical abortion, and reported the mean maximum pain score in the

usual-care group to be 60 with a standard deviation of 25. To detect a difference of at least 15-mm with 80% power and a two-sided alpha of 0.05, this study required at least 43 analyzable participants per study group. We expected that approximately 20% of participants, enrolled in the waiting room, would not have an aspiration procedure the same day. Thus, we over-enrolled by 20% in anticipation of these losses.

The focus of the primary analysis was the difference in maximum pain score between groups. Group assignments remained blinded throughout the analysis. We used IBM SPSS Statistics for Windows,



**Fig. 2.** Participant flow chart for trial of women randomized to acupuncture plus usual care\*, placebo plus usual care, or usual care alone during first trimester abortion (N=153). \*Usual care consisted of ibuprofen 800 mg orally 1 h before the procedure and a paracervical block immediately prior to the procedure. †A procedure was not performed if participants had a complete abortion, declined an office procedure, or wanted more time to consider her plan. \*1 participant excluded from the usual care group due to a randomization error; 1 participant each from the remaining groups excluded due to a procedure not being completed after randomization.

**Table 1**  
Baseline characteristics of women randomized to acupuncture plus usual care, placebo plus usual care, or usual care alone during first trimester abortion ( $N=153$ ).

Variable	Acupuncture ( $n=53$ )	Placebo ( $n=50$ )	Usual Care ( $n=50$ )
Age (y), mean $\pm$ SD	31.0 $\pm$ 6.8	28.7 $\pm$ 6.9	30.9 $\pm$ 7.6
Parity, n (%)			
0	21 (40)	16 (32)	17 (34)
1	12 (22)	18 (36)	13 (26)
2+	20 (38)	16 (32)	20 (40)
Pregnancy type			
Induced abortion	39 (74)	34 (68)	33 (66)
Spontaneous abortion	14 (26)	16 (32)	17 (34)
Race/ethnicity, n (%)			
Hispanic	43 (81)	39 (78)	39 (78)
Non-Hispanic White	6 (11)	4 (8)	5 (10)
Non-Hispanic Black	1 (2)	5 (10)	4 (8)
Other*	3 (6)	2 (4)	2 (4)
Insurance, n (%)			
Medicaid	43 (81)	41 (82)	41 (82)
Commercial	10 (19)	9 (18)	9 (18)
Education, n (%)			
<High school	11 (20)	8 (16)	10 (20)
Completed high school	12 (23)	20 (40)	12 (24)
Some college	12 (23)	12 (24)	12 (24)
Bachelor or more	18 (34)	10 (20)	16 (32)
Employment**, n (%)			
Working	30 (56)	30 (60)	22 (45)
School	3 (6)	4 (8)	7 (14)
Both	4 (8)	4 (8)	5 (5)
Neither	16 (30)	12 (24)	15 (34)
Anxiety history**, n (%)	5 (9)	7 (14)	4 (8)
Depression history**, n (%)	5 (9)	10 (20)	4 (8)
Acupuncture history, n (%)	20 (38)	10 (20)	16 (32)
Baseline pain, median (IQR)	0 (0, 5)	0 (0, 5)	0.0 (0, 44)
Baseline anxiety, median (IQR)	50 (25–65)	50 (20–52)	50 (10–70)

Includes women who self-identified as Asian (4), Hawaiian (1), Native American (3). IQR – interquartile range.

\*\* One woman declined to report employment history in the usual care group; one woman declined to report history of anxiety in the acupuncture group; two women declined to report history of depression in the acupuncture group.

version 24 (IBM, Armonk, NY, USA) to evaluate categorical variables with the Pearson chi-square test or Fisher's Exact test; for VAS scores, we used both non-parametric testing (Kruskal-Wallis and Mann-Whitney tests) as well as analysis of variance (ANOVA). Due to VAS scores being non-normally distributed, we report median scores as the primary outcome, but for ease of comparison with other studies, we also report mean scores in the Supplementary Table.

### 3. Results

The study staff screened 280 women. One hundred one women declined participation, or were ineligible due to an allergy to ibuprofen.

**Table 2**  
Pain and anxiety scores recorded immediately following first-trimester abortion among women randomized to acupuncture plus usual care, placebo plus usual care, or usual care alone ( $N=150$ ).

Variable	Acupuncture ( $n=52$ )	Placebo ( $n=49$ )	Usual Care* ( $n=49$ )	p-value**
Pain (mm on VAS)				
Maximum pain, median (IQR)	39.5 (11, 63)	70.0 (1, 81)	71.0 (33, 90)	<0.01
Change*** from baseline (IQR)	+21.0 (1.5, 52.5)	51.0 (23, 79)	47.0 (20, 74)	.01
Anxiety (mm on VAS)				
Maximum anxiety, median (IQR)	11.5 (0.5, 30)	31 (2, 67)	44.0 (3, 80)	.01
Change from baseline (IQR)	–27.5 (–50, 2)	0 (–30, 10)	2.0 (–10, 30)	<0.01

VAS – Visual analog scale, IQR = interquartile range.

\* Usual care included ibuprofen and paracervical block for all participants.

\*\* p-value obtained by Kruskal-Wallis Test.

\*\*\* Change calculated as (post procedure pain – pre procedure pain) or (post procedure anxiety – pre procedure anxiety).

Twenty-six women who enrolled did not undergo randomization because either no procedure took place or no interventionist was available at the time of the procedure (Fig. 2). Thus, we randomized 153 participants. We excluded three women, one in each group, after randomization. The final analysis included 150 participants: 52 participants in the auricular acupuncture group, 49 in the placebo group, and 49 in the usual care group (Fig. 2). Study enrollment occurred from August 2017 to May 2018.

The baseline characteristics of the participants in all three groups were similar (Table 1). Participants ranged in age from 18–45 years old, most identified as Hispanic (79%), and were insured by Medicaid (82%). Sixty-nine percent presented for induced abortion and 31% presented for care of a spontaneous abortion. Self-reported history of anxiety or depression was uncommon (10.5% and 12.4% respectively). Thirty percent reported any previous acupuncture use. Table 1 presents the baseline pain and anxiety scores.

The median maximum pain scores between the auricular acupuncture, placebo, and usual care groups were meaningfully different [39.5 (IQR 11, 64.5); 70.0 (IQR 40.5, 84); 71.0 (IQR 32, 91.5), respectively,  $p<0.01$ ] (Table 2). The auricular acupuncture group median pain score was 31.5 mm lower than the usual care group, and similarly lower than the placebo group. The auricular acupuncture group also reported lower anxiety scores compared to both placebo and usual care groups [11.5 (IQR 0.25, 30); 31.0 (IQR 2.0, 68.5); 44.0 (IQR 2.5, 80); respectively,  $p=.01$ ] (Table 2).

Pain and anxiety scores were highly similar whether the participants received care from an interventionist who was a licensed acupuncturist or a gynecologist (data not shown). Results were also similar among Spanish-speaking and English-speaking participants. Finally, results were similar stratifying for diagnosis (spontaneous abortion versus induced abortion). We identified no acupuncture-related adverse events. At exit from the study, 94% of women who underwent acupuncture rated their overall care as good or very good compared to 76% in the usual care group; 63% in the acupuncture group compared to 48% in the usual care group rated the “degree to which my pain was controlled” as good or very good.

About three-quarters of the 99 participants in both the acupuncture (78%) and placebo (73%) groups correctly identified their treatment assignment. English-speaking women were more likely to identify their treatment as placebo (63%), and Spanish-speaking participants were more likely to identify their treatment as acupuncture (68%). Within the acupuncture treatment group, women who incorrectly guessed the treatment was placebo had higher pain scores than women who correctly guessed their treatment was acupuncture. Conversely, within the placebo group, participants who incorrectly guessed their treatment was acupuncture had lower pain scores than women who correctly guessed they had received placebo. These subgroup differences are not suitable for statistical analysis because the subgroups are quite small. Those who actually received acupuncture had lower pain scores than women who received placebo, no matter what they believed they had received.

#### 4. Discussion

This randomized, three-arm trial demonstrated that women receiving auricular acupuncture prior to uterine aspiration for first trimester abortion reported a lower level of maximum pain during the procedure compared to women receiving placebo or usual care alone. Participants receiving usual care were not blinded. Participants assigned to the placebo intervention and those assigned to usual care reported similar pain scores. Most women assigned to the placebo intervention (73%) suspected they did not receive acupuncture indicating that our attempted treatment blinding had limited success. We asked women what treatment they thought they had received after the abortion procedure was complete and we did not ask specifically if they could feel any pinprick in their ears; possibly, those women who experienced the most procedure pain guessed they had not received the acupuncture, while those who experienced less pain guessed they had received effective treatment with acupuncture. Since subgroup pain scores were lower in the acupuncture group whether or not women identified their treatment correctly, a placebo effect seems unlikely to explain the 30-point difference in the post-procedure pain scores between the groups. In addition to the lower pain scores, women receiving auricular acupuncture also reported lower maximum anxiety scores compared to the placebo and usual care groups.

Minimizing use of opiates and benzodiazepenes for sedation, pain, and anxiety is an urgent goal throughout medical care [23]. Auricular acupuncture is a low-cost intervention compared to moderate or complete sedation with anesthesia. Giving anesthesia requires staff licensed to perform sedation along with equipment for intubation and monitoring of heart and lungs, and the anesthetic agents themselves. Post-anesthesia, women typically need transportation home which increases costs and limits privacy. In contrast, this auricular acupuncture protocol uses low-cost, sterile, single-use press-on needles, is easily learned in a few hours, and in many states does not require additional licensure.

Other studies also suggest that acupuncture can provide relief for peri-operative pain for gynecological surgical procedures and that treated women used fewer pain medications in post op recovery and at home [24,25]. The present study did not assess post-procedure pain or analgesic use, an area for further study. Dysmenorrhea is cyclic uterine cramping that may be similar to pain during uterine aspiration; evidence that acupuncture may alleviate dysmenorrhea [17,20,26] adds some plausibility to our findings that auricular acupuncture relieves cramps associated with uterine aspiration.

In conclusion, our study demonstrated the Gold Protocol for auricular acupuncture was effective in reducing pain during a first-trimester uterine aspiration. In addition, auricular acupuncture effectively reduced anxiety, a known modulator of perceived pain. Given these promising results, exploring the efficacy of this protocol to manage pain and anxiety associated with other gynecologic procedures such as intrauterine device insertion and medical abortion will be useful. Given the weak or inconsistent results in previous acupuncture studies, a research priority should be to replicate these results before widespread training and dissemination. Additional research is also needed to explore the efficacy of using acupressure seeds or pellets as an acupoint stimulant rather than acupuncture needles because using acupressure would not be subject to the level of regulation that can prevent widespread use of the needle intervention studied here.

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.contraception.2018.11.016>.

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