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SHORT REPORT

Women's Experience of Living with Vulvodynia Pain: Why They Participated in a Randomized Controlled Trial of Acupuncture

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Abstract

Introduction: Vulvodynia is vulvar pain lasting at least 3-months without clear identifiable cause that may have other associated factors. The aim, to explore motivations of women participating in a double-blind randomized controlled trial of acupuncture for vulvodynia.

Methods: Responses to the question: “Tell me about why you decided to participate in this study” were analyzed using conceptual content analysis to identify patterns in motivation for study participation.

Results: Four patterns emerged: 1) *desire to address uncontrolled pain*, 2) *desire for understanding*, 3) *wish to contribute to knowledge generation*, and 4) *need to remove cost barriers*.

Conclusion: Motivations indicate vulvodynia-specific aspects of acceptability of acupuncture.

Clinical Trial Registration: NCT03364127.

Keywords: vulvodynia, vulvar pain, acupuncture, complementary integrative health

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Introduction

UP TO 7% OF WOMEN have vulvodynia, disabling chronic vulvar pain of at least a 3-month duration without a clear identifiable cause that may have other associated factors.¹ Vulvodynia is often accompanied by dyspareunia, painful intercourse, which renders sexual intercourse virtually impossible.² Despite taking adjuvant drugs and opioids, women with vulvodynia reported 6.7/10 average pain intensity (average of current, least, and worst pain in the last 24 h).³ In one study, 60% of women used alcohol and 43% combined alcohol and analgesics, including opioids, to reduce their pain.³ Many vulvodynia treatments are inconsistently effective.¹ Thus, treating vulvodynia can be “hit or miss,” leaving women desperate for relief.

Acupuncture has demonstrated efficacy for several chronic pain conditions.^{4,5} A pilot randomized controlled trial (RCT) for vulvodynia⁶ showed that acupuncture significantly reduced vulvar pain and dyspareunia and increased overall sexual function. We are in the fifth year of a National Institutes of Health-sponsored double-blind efficacy study of a 5-week trial of genuine acupuncture versus sham acupuncture for the treatment of vulvodynia (both acupuncturist and participant blinded to the needle type). Because little is known about why patients with chronic pain choose to participate in acupuncture research, we report on women's motivations to participate in this double-blind RCT of acupuncture for vulvodynia.

The Institutional Review Board (IRB) at the University of Illinois Chicago (UIC, IRB2017-0885) approved the RCT, and the IRB at the University of Florida approved the study of deidentified data as exempt (IRB201800566).

Methods

Design

After the 10th and final acupuncture session,⁷ participants were asked to respond to one question: “Tell me about why you decided to participate in this study.” Participants typed open-ended responses into the vulvodynia module of PAIN-ReportIt,⁸ a computerized McGill Pain Questionnaire. Informed consent was obtained from all enrolled. Data collection and management were facilitated by the Research Electronic Data Capture (REDCap),⁹ hosted at UIC. This trial is registered in ClinicalTrials.gov, Identifier: NCT03364127.

Sample/setting

The inclusion criteria were as follows: 18 years of age or older, diagnosed with vulvodynia on-site by a pelvic examination, and never had acupuncture. The exclusion criteria were as follows: other pathologic causes of vulvar pain, pelvic pain, pregnancy, atrophic vaginitis, and concomitant use of massage, physical therapy, or additional acupuncture. This study is being conducted in the Integrative Medicine Research Lab at the UIC College of Nursing. Participants were recruited from the Chicagoland area.

Analysis

Participants' responses were analyzed using conceptual content analysis to code for existence and frequency of concepts reflecting motivation of study participation.

Results

The 50 participants were 20 to 52 years old (mean \pm standard deviation = 29.0 \pm 7.1) and predominately White, non-Hispanic, single, and educated beyond high school (Table 1). Four motivational patterns emerged from participants' responses on why they participated in the study. Representational quotes for each of these 4 patterns are provided (Table 2).

A desire to address uncontrolled pain was reported by 39 women (78%). Untreated and uncontrolled chronic pain was described as all-consuming and leaving women feeling desperate. Several linked their uncontrolled pain to negative effects on partner intimacy, their own mental health, and to poorer overall quality of life. One 29-year-old White woman wrote, “I have been dealing with vulvodynia for 7 years now. It consumes my life. It has cost me a lot of money, time, and intimacy with partners. I am willing to do almost anything for the pain to get better.” Many participants noted that nothing has worked for them in the past, so they are willing to try new treatments to reduce their pain.

A wish to contribute to knowledge generation was reported by 13 women (26%). Those noting this motivation ranged across all education levels. Many wanted to contribute to science, noting it would promote a greater understanding of vulvodynia and acupuncture as a potential treatment. Participation made them hope that solutions would be found to minimize the suffering for women with vulvodynia. A 28-year-old White woman expressed this sentiment by writing “I participated because I wish we had more research on this subject. I'm grateful to contribute to growing research and to help those currently suffering and hopefully help people from going without treatment and answers.”

A desire for understanding oneself was noted by seven women (14%). Many wanted to better learn about their own experience with vulvodynia and ways to manage their pain. Some

TABLE 1. CHARACTERISTICS OF THE SAMPLE (N=50)

Variable	Category	Total (N=50), n (%)
Marital status	Single	29 (58)
	Married/partnered	18 (36)
	Widowed	1 (2)
	Other	2 (4)
Race	White	40 (82)
	Black	1 (2)
	Asian	4 (8)
	Native American/Alaska Native	1 (2)
	Other	3 (6)
Ethnicity	Hispanic	10 (20)
	Not Hispanic	40 (80)
Income	<51k	25 (50)
	51–100k	16 (32)
	>100k	9 (18)
Education	<HS, HS, vocational school	5 (10)
	Associates/some college	2 (4)
	Bachelor's degree	25 (52)
	Graduate or professional	16 (33)
Employment status	Unemployed	1 (2)
	Employed (part- or full-time)	44 (88)
	Student	5 (10)

TABLE 2. REPRESENTATIVE QUOTES FOR EACH OF THE FOUR MOTIVATIONAL PATTERNS REFLECTING WHY WOMEN DECIDED TO PARTICIPATE IN THIS ACUPUNCTURE STUDY

<i>Characteristics^a</i>	<i>Quotes</i>
A desire to address uncontrolled pain 37-year-old ^a White, Hispanic/Latino, income >100k	I've tried many things to reduce my vulvodynia pain, but nothing has worked. I want to try all my available options before accepting that my pain will not go away.
24-year-old White, income 51–100k	I wanted to participate in this study in order to relieve my pain and not be anxious about having sex—because of the thought of being in pain.
33-year-old ^a White, income >100k	I have had vulvodynia for over a decade, and I haven't had good luck with traditional treatment, or with even finding clinicians who are familiar working with it. I mostly ignore it, but I know that's not healthy. I thought this would be a good way to try something new and begin addressing it again.
20-year-old ^a White, income <51k	I desperately want the pain to go away so I can feel like I can have a closer bond with my partner and relate to my peers.
31-year-old ^a White, Hispanic/Latino, income 51–100k	I have been told that there is no treatment for vulva. I am in love with my husband, we used to have lot of sex and now our marriage is fallen apart. I feel less of a woman I cry out of nowhere my mood swings are crazy. I would love to feel how I used to; I would love to make love to him without having to worry about causing myself pain. If I have to volunteer to help other women or myself, I will not hesitate. No woman should feel less.
28-year-old ^a White, income <51k	I've been suffering from vulvodynia for over four years and have tried a number of different treatments including medication and physical therapy. However, my pain has never gone away. I felt like it was time to explore some alternative treatments that might reduce the pain. For the most part, I've made some peace with the fact that my pain might never disappear. However, I still want to explore options that would lessen it. I know acupuncture has been used to successfully treat pain for other people in my life, so I wanted to try it as well.
A desire for understanding oneself 35-year-old ^a White, Hispanic/Latino, income <51k	To become more aware of my condition and try to find solutions to help it.
32-year-old White, <51k	To achieve better understanding of my pain and options/methods for management.
22-year-old Black, <51k	I had vaginal pain for a while and never understood why and I thought this study would provide answers, which it did. I also just wanted to contribute.
22-year-old White, <51k	I've had a burning pain in my vagina over the past three years that has never been treated or diagnosed, besides once being told I should use lube during sex, even though I tried to make clear that was not the main problem I was experiencing.
A wish to contribute to knowledge generation 37-year-old ^a White, income 51–100k	Wanted to be a part of increasing the research understanding of treatment for vulvodynia. Also, so I could document it for my closed Facebook group. Also, for personal: maybe it would help me.
23-year-old ^a Black, Hispanic/Latino, income 51–100k	I know how important research is to solve future needs.
28-year-old ^a White, income 51–100k	I participated because I wish we had more research on this subject. I'm grateful to contribute to growing research and to help those currently suffering and hopefully help people from going without treatment and answers.
31-year-old ^a White, income 51–100k	I wanted to try an alternative treatment. I also want to support this area of research that is traditionally neglected/overlooked since it mostly affects women or people with vulvas.
A need to remove cost barriers 25-year-old White, income <51k	I was hopeful that this would be the answer to my pain, and acupuncture can be very expensive on its own.
56-year-old ^a White, income 51–100k	I'm hoping that acupuncture may someday be covered by HMO insurance.
26-year-old White, income <51k	I want to be active in combatting my pain, but I've currently switched health insurance and don't have the money to pay for treatments out of pocket. I've also been curious about acupuncture.
25-year-old ^a White, income >100k	Free/streamlined treatment I would not otherwise have had access to. I've tried multiple medications and physical therapy with little success, so I'm willing to do anything at this point!

^aMarried/partnered.

had never even had a diagnosis or were not aware that their pain was abnormal. A 28-year-old Hispanic woman exemplified this when she wrote, "I didn't know that experiencing pain through inserting a tampon or going to the gynecologist and of course having sex wasn't the norm. I have been afraid of all of these things simply to avoid pain and when I saw the ad on the bus, I couldn't believe this was a condition of some sort that could be treated or tended to. It had made me completely reevaluate how I perceive my own pain and that's been strangely freeing!"

A need to remove cost barriers was expressed by 5 (10%) women, all identifying as White and from five different income brackets ranging from less than \$11,000 to more than \$100,000. Some were motivated to participate because they could not afford to pay for acupuncture on their own because insurance did not cover it. One 26-year-old White woman wrote, "I want to be active in combatting my pain, but I've currently switched health insurance and don't have the money to pay for treatments out of pocket." Another participant wrote that she hoped that acupuncture would someday be covered by insurance.

Limitations

The limitation of this study is that participants were asked why they chose to participate in the study after they completed the acupuncture intervention. Their responses may have differed depending on whether they had pain relief.

Discussion

Most participants cited their uncontrolled pain as motivation to participate. This finding is consistent with Li et al's¹⁰ findings that showed adults with sickle cell disease sought acupuncture to reduce uncontrolled pain. Importantly, until learning of and participating in this study, several women did not have a diagnosis or reason for their vulvar pain. This is consistent with Harlow and Stewart's findings that it takes visits to at least three providers for a diagnosis and that some women never get a diagnosis.¹¹ Increased public health awareness as well as health care provider and student education regarding the existence of vulvodynia is warranted.

Further investigation is needed concerning women's experiences of living with uncontrolled vulvodynia. This includes several factors: lack of awareness that vulvar pain is abnormal, sharing their pain experiences with health care providers, and/or dismissal of experiences by providers. Future research is warranted into complex societal constructs related to stigma and lack of understanding of one's body, and how these societal constructs influence how women with vulvodynia view themselves and suffer in silence. Investigations into patient-reported outcomes should also aim to capture the experience of living with an undiagnosed pain condition. These insights will work to reduce stigma, enable better understanding of vulvodynia, and lead to new targeted treatments, including acupuncture. Many participants were committed to new knowledge generation so that others who suffer from vulvodynia may be helped.

Some women participated to reduce health care costs. Acupuncture is not currently covered by most third-party insurances and Medicaid and Medicare do not cover it for the treatment of vulvodynia.¹² If this RCT demonstrates efficacy, then financial barriers to acupuncture must be addressed through the next step, conducting a hybrid

effectiveness-implementation trial of acupuncture for vulvodynia. A pragmatic trial will enable embedding acupuncture for treating vulvodynia into the American health care system.¹³ Conducting pragmatic trials of acupuncture is a high research priority as delineated in the National Center for Complementary and Integrative Health 2021–2025 Strategic Plan.¹⁴ Importantly, pragmatic trials of acupuncture will impact health care policy regarding prompt third-party insurance, Medicaid, and Medicare reimbursement. This policy shift will enable acupuncture to be accessible to all and allow integration into conventional clinical care.

The motivations of participants in this study reflect several domains of Sekhon's Theoretical Framework of Acceptability.¹⁵ A desire to address uncontrolled pain and a desire for understanding oneself overlap with the constructs of affective attitudes or how the individual feels about the intervention and its perceived effectiveness. A wish to contribute to knowledge generation is similar to intervention coherence or a person's understanding of how the intervention and how science works as well as perceived effectiveness.¹⁵ The fourth pattern, a need to remove cost barriers, brings together Sekhon's categories of opportunity costs, the perceived benefits gained from engaging in the intervention as well as the burdens, or perceptions about the effort required to participate in the intervention.

Conclusion

The motivations of women who participated in this double-blind RCT of acupuncture indicate vulvodynia-specific aspects of acceptability of acupuncture for women with this chronic pain condition. These motivations and elements of acceptability can help guide future studies of acupuncture for vulvodynia as well as using this therapy to treat other chronic pain conditions.

Authors' Contributions

A.A.D., C.L.P., and J.M.S. were responsible for the acquisition, interpretation, and drafting of the article. A.A.D., A.D.S., L.A.B., Y.Y., C.L.P., and N.T. substantially contributed to the data analysis. M.L.S., J.E.G., W.H.K., M.M., M.T., H.Y., T.J.K., D.J.W., and D.F. critically revised the work for important intellectual content. All authors provided final approval of the version to be published and agree to be accountable for all aspects of the work.

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References

- Bornstein J, Goldstein AT, Stockdale CK, et al. 2015 ISSVD, ISSWSH, and IPPS consensus terminology and classification of persistent vulvar pain and vulvodynia. *J Sex Med* 2016;13(4):607–612; doi: 10.1016/j.jsxm.2016.02.167.
- Basson R. The recurrent pain and sexual sequelae of provoked vestibulodynia: A perpetuating cycle. *J Sex Med* 2012; 9(8):2077–2092; doi: 10.1111/j.1743-6109.2012.02803.x.
- Schlaeger JM, Pauls HA, Powell-Roach KL, et al. Vulvodynia, “A Really Great Torturer”: A mixed methods pilot study examining pain experiences and drug/non-drug pain relief strategies. *J Sex Med* 2019;16(8):1255–1263; doi: 10.1016/j.jsxm.2019.05.004.
- Vickers AJ, Cronin AM, Maschino AC, et al. Acupuncture for chronic pain: Individual patient data meta-analysis. *Arch Intern Med* 2012;172(19):1444–1453; doi: 10.1001/archinternmed.2012.3654.
- Vickers AJ, Vertosick EA, Lewith G, et al. Acupuncture for chronic pain: Update of an individual patient data meta-analysis. *J Pain* 2018;19(5):455–474; doi: 10.1016/j.jpain.2017.11.005.
- Schlaeger JM, Xu N, Mejta CL, et al. Acupuncture for the treatment of vulvodynia: A randomized wait-list controlled pilot study. *J Sex Med* 2015;12(4):1019–1027; doi: 10.1111/jsm.12830.
- Schlaeger JM, Takakura N, Yajima H, et al. Double-blind acupuncture needles: A multi-needle, multi-session randomized feasibility study. *Pilot Feasibility Stud* 2018;4(1): 72; doi: 10.1186/s40814-018-0265-9.
- Wilkie DJ, Judge MKM, Berry DL, et al. Usability of a computerized PAINReportIt in the general public with pain and people with cancer pain. *J Pain Symptom Manage* 2003; 25(3):213–224; doi: 10.1016/s0885-3924(02)00638-3.
- Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42(2):377–381; doi: 10.1016/j.jbi.2008.08.010.
- Li H, Patil CL, Molokie RE, et al. Acupuncture for chronic pain in adults with sickle cell disease: A mixed-methods pilot study. *Acupunct Med* 2021;39(6):612–618; doi: 10.1177/09645284211017303.
- Harlow BL, Stewart EG. A population-based assessment of chronic unexplained vulvar pain: Have we underestimated the prevalence of vulvodynia? *J Am Med Womens Assoc* (1972) 2003;58(2):82–88.
- Mao JJ, Davis RT, Coeytaux R, et al. Acupuncture for chronic low back pain: Recommendations to Medicare/Medicaid from the Society for Acupuncture Research. *J Altern Complement Med* 2019;25(4):367–369; doi: 10.1089/acm.2019.29067.jjm.
- Curran GM, Bauer M, Mittman B, et al. Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care* 2012;50(3):217–226; doi: 10.1097/MLR.0b013e3182408812.
- Langevin HM. Moving the complementary and integrative health research field toward whole person health. *J Altern Complement Med* 2021;27(8):623–626; doi: 10.1089/acm.2021.0255.
- Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: An overview of reviews and development of a theoretical framework. *BMC Health Serv Res* 2017;17(1):88; doi: 10.1186/s12913-017-2031-8.

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