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University of Illinois at Chicago
Research Information and Consent/Authorization for Participation in Research

EFFECT OF ACUPUNCTURE ON PATIENT VULVODYNIA OUTCOMES

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

The Principal Investigator for this research is:

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About This Research Study

You are being asked to be a subject in a research study to see if acupuncture can be used to treat or control pain due to vulvodynia. Vulvodynia is a women's pain condition, and women with vulvodynia have pain in their vulva, the genital area outside their vagina. They also have pain when they have sexual intercourse or insert anything in the vagina. Sometimes they have so much pain that they cannot have sex. If acupuncture can help in decreasing vulvodynia pain, we also want to find out how long this effect lasts. Some studies have shown that acupuncture may help control this pain, but we need to study this treatment more in-depth.

You have been asked to participate in the research because you told us that you have vulvodynia and you have not responded well to the current treatments, and you may be eligible to participate.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago (UIC) or the University of Illinois Hospital and Health Sciences System (UI Health). **If you decide to participate, you are free to withdraw at any time without affecting that relationship.**

Approximately 130 subjects may be involved in this research at UIC.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	We are conducting this study to find out if acupuncture can be used to treat or control pain due to vulvodynia, a women's pain condition that results in pain in the vulva or genital area outside the vagina, and during sexual intercourse.
WHAT WILL HAPPEN TO ME DURING THE STUDY?	If you participate in this study, you will be assigned by chance to receive acupuncture treatments with either regular acupuncture needles or with placebo needles. A placebo needle is a needle that does not penetrate the skin like a regular acupuncture needle does. For more information, please see the "What Procedures Are Involved?" section below.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	The study involves 10 acupuncture treatments, two treatments every week for about 5 weeks. Each treatment is expected to last about one to one and a half hours. After the 5 weeks and all the acupuncture treatments, we may ask you to complete a very short pain questionnaire at home once a week for up to an additional12 weeks.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	There may be no direct benefit to you from participation in this research, but we expect that the knowledge gained from this study will provide important information to help us develop acupuncture treatments in the future for the control and relief of vulvodynia pain.
WHAT ARE THE MAIN RISKS OF THE STUDY?	This study has minor risks. There is a small risk of mild bruising, soreness or bleeding after the acupuncture needle is withdrawn. There is a risk that you may experience a negative reaction from acupuncture and thereby experience worse symptoms from participation in the study. You may feel mild discomfort upon needle insertion, but this will go away once the needle has been inserted. There is a risk that some of the questions in the questionnaires may make you uncomfortable, nervous or tired. There is also a minor risk of loss of privacy or confidentiality. For details and a list of risks you should know about, please see the "What Are the Potential Risks and Discomforts of the Study" section below.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	You have the option to not participate in this study.

QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact: Judith M. Schlaeger, PhD, CNM, LAc – Principal Investigator (312) 413-4669 (work) jschlaeg@uic.edu Marie L. Suarez, PhD - Project Director (312) 413-5459 (work) mlsuarez@uic.edu If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu. If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois HIPAA Privacy Office at (844) 341-2201 or hipaa@uillinois.edu.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the study team questions at any time.

What procedures are involved?

This research will be conducted at the UIC College of Nursing and you will participate in the study for up to about 17 weeks. For the first 5 weeks you will come to the College of Nursing two times a week for acupuncture treatments. We may also ask you to complete a short weekly questionnaire at home for up to an additional 12 weeks.

The research procedures are as follows:

- Once you agree to participate, we will ask you to insert and remove a tampon as a stimulus to cause pain, and you will tell us your level of pain. After that, you will complete five questionnaires about (1) your pain, (2) your sexual function and sexual activities, and (3) how your pain affects your everyday life. We will also perform a gynecological screening exam at the UIC College of Nursing or the UIC hospital to confirm that you do have vulvodynia and determine the type of vulvodynia you have. If these exams show that you do not qualify, you will not be able to continue participating in the study.

- If you qualify for the study, you will be randomly assigned (like flipping a coin) to one of two groups. The groups will receive acupuncture treatments with either regular acupuncture needles or with placebo needles. A placebo needle is a needle that does not penetrate the skin like a regular needle does. If you are assigned to the placebo needle group, you will be offered 10 free regular acupuncture sessions at the end of the study.

- The study involves 10 acupuncture treatments, two treatments every week for about 5 weeks. In each session, the acupuncturist will insert 13 needles into 13 points in your body. The needles will remain in place for 45 minutes, after which the acupuncturist will remove all the needles. Each session is expected to last about one to one and a half hours.

- At one of the 10 visits we will ask you to complete other questionnaires related to adverse childhood experiences, stressful life events, and your perception of pain. This is expected to take about 20 minutes.

- After the 10th acupuncture treatment we will ask you again to insert and remove a tampon, tell us your level of pain, and complete the five questionnaires about your pain, sexual function and activities, and how your pain affects your everyday life. At the end of the study, you will also complete a short questionnaire to let us know which method of acupuncture you think that you received. The first and last sessions may last up to 2.5 – 3 hours.

- Before the first acupuncture session and once a week before an acupuncture treatment, you will provide us with a urine sample for a pregnancy test. If it is positive you will not be able to continue in the study because some of the acupuncture points should not be used on pregnant women.

- After all the acupuncture treatments, we may ask you to complete a short pain questionnaire at home once a week for up to12 weeks, right after you insert and remove a tampon. This information will help us to determine how long the effect of the acupuncture lasts.

- You need to complete all 10 study visits within the 5 week period. If you miss one visit you will not be able to continue in the study. Participants must complete all visits so that we can clearly determine the effect of our acupuncture protocol on vulvodynia pain and symptoms.

- On your first visit, as part of the gynecological screening exam, we would like to take a picture of your vulvar area. We have observed that some women with vulvodynia have red to purple stripes in their vulva. These color changes have not been documented before. We want to study if these red stripes may be used in diagnosing vulvodynia. We also want to use this information to teach other clinicians to diagnose vulvodynia and present at scientific meetings if you allow us. The picture will not show your face or any area outside of the vulvar area. If you do not agree to have your picture taken, you will still be able to participate in the study.

  I allow my vulvar area to be photographed for research purposes:

  ☐ YES ☐ NO

  I allow the researchers in this study to use my picture to help in teaching other clinicians in diagnosing vulvodynia and present at scientific meetings:

  ☐ YES ☐ NO

What are the potential risks and discomforts?

This study has minor risks. There is a small risk of mild bruising, soreness or bleeding after the acupuncture needle is withdrawn. There is a risk that you may experience a negative reaction from acupuncture and thereby experience worse symptoms from participation in the study. You may feel mild discomfort upon needle insertion, but this will go away once the needle has been inserted. To avoid or minimize these risks, only experienced licensed acupuncturists will perform the acupuncture. There is a risk that some of the questions in the questionnaires may make you uncomfortable, nervous or tired, but you do not have to answer any questions that you prefer not to

answer. There is also the risk of loss of privacy or confidentiality, but we will avoid this risk as much as possible.

There is also a risk that your picture will be exposed without our knowledge. However, the camera we will use will be a stand-alone camera, not connected to the Internet; the pictures will be downloaded from the camera immediately to a secure and password protected folder and deleted from the camera right away; and the pictures' label will indicate whether they can be shared or not.

What are the reproductive risks?

As mentioned above, participating in this research may involve risks to pregnant women and/or an unborn baby which are currently unforeseeable. To protect against possible side effects of the acupuncture treatment, if you are pregnant you may not take part in this study. If you think that you have become pregnant during the study, tell the researchers immediately. We will test you every week to see if you are pregnant. As stated above, if you become pregnant, your participation will be stopped.

Will I be told about new information that may affect my decision to participate?

During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Are there benefits to taking part in the research?

There may be no direct benefit to you from participation in this research, but we expect that the knowledge gained from this study will provide important information to help us develop acupuncture treatments in the future for the control and relief of vulvodynia pain.

What other options are there?

You have the option to not participate in this study. If you decide not to participate, you can still receive acupuncture from an acupuncture provider outside of the study.

What about privacy and confidentiality?

Only the study team (researchers and investigators on this study) will have access to study information, and, if appropriate, your physician or nurse. Study information which identifies you and the consent form signed by you will be looked at and/or copied for examining the research by:

- UIC Office for the Protection of Research Subjects
- Food and Drug Administration (FDA)
- The National Institutes of Health, the funding agency

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research. To minimize this risk, you will be assigned a code number linked to your information, and your research data and your picture will be identified only with this code number. All electronic data will be saved and stored in a secure server at the University of Florida under the control of Dr. Diana J. Wilkie, one of the study coinvestigators. The electronic data will only have your code number and will not include your

name or any other identifiable information. Paper data will be kept in a locked office at the UIC College of Nursing. We will destroy the link between your personal information and your code six years after completion of the study. When results of the research are published or presented at conferences, no information will be included that will reveal your identity.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

To help us protect you and the information we will be collecting from you, this research has been given a Certificate of Confidentiality by the U.S. government. This Certificate means that researchers cannot be forced, even by courts or the police, to disclose any information about you.

The Certificate does not stop you from disclosing, or agreeing in writing to allow researchers to disclose, information about you. For example, if you would like an employer or insurer to know something about you that is documented in this research, you can write and sign a statement telling the researchers it is okay to give your employer or insurance company information.

Will health information about you be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing Dr. Judith Schlaeger and the research team to create, get, use and store protected health information that identifies you for the purposes of this research.

The health information includes all information created and/or collected during the research as described in this consent form, including: vulvodynia diagnosis, results of your gynecological exam, medications, treatments, pain and symptoms, and demographic information (name, address, telephone number, date of birth, gender, ethnicity, marital status, religion, education level, occupation/employment status, income), as well as self-reported information about your pain, sexual function and quality of life.

During the conduct of the research, the researchers may use or share your health information:

- With each other and with other researchers involved with the study;
- With law enforcement or other agencies, when required by law;
- With the University of Illinois at Chicago Institutional Review Board, if necessary to protect your safety.

This information will not be shared with anybody outside of the research team. If all information that identifies you is removed from your health information, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used by the researchers (as permitted by law) for other purposes, such as other research projects.

You will not have access to the health information related to this research study until the study is done. However, this information is available to your doctor in the case of an emergency. However, the researcher may not give you access to the research records or information that is not usually kept in your medical record, as it is not required by HIPAA.

How will your health information be protected?

The researchers agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, if permitted by laws that they have to follow.

What if I am injured as a result of my participation?

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Schlaeger at telephone number (312) 413-4469.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of an UIC employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

What are the costs for participating in this research?

There are no costs to you for participating in this research. You will not be billed for acupuncture received during this research study, nor for any regular follow-up acupuncture you may be offered after the end of the study.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will not be offered payment for being in this study. However, you will receive $10 every time you come to a study visit to cover transportation and parking expenses.

Can I withdraw or be removed from the study?

Taking part in this study is voluntary. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care at UIC. Your

Authorization for release of health information for this research study does not have an expiration date, but can be canceled sooner if you decide to withdraw your permission You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to: Dr. Judith Schlaeger, UIC College of Nursing, Suite 856, 845 South Damen Avenue, Chicago, IL 60612.

You have the right to leave a study at any time without penalty. The researchers also have the right to stop your participation in this study without your consent if:

- they believe it is in your best interest
- you become pregnant
- you miss one of the acupuncture treatments

In the event you withdraw or are asked to leave the study, you will still receive the $10 for the current visit.

If you cancel this authorization, you may no longer be allowed to take part in the research study. Even if you cancel this authorization, we will not obtain any additional health information from you, but the researchers may still use and disclose the health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

Who should I contact if I have questions?

Contact the researchers (below) if you have any questions about this study or your part in it, or if you have questions, concerns or complaints about the research.

Judith M. Schlaeger, PhD, CNM, LAc – Principal Investigator
(312) 413-4669 (work)
(708) 334-1097 (cell)
jschlaeg@uic.edu

Marie L. Suarez, PhD - Project Director
(312) 413-5459 (work)
mlsuarez@uic.edu

What are my rights as a research subject?

If you have questions about your rights as a research subject or concerns, complaints, or to offer input you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois at Chicago Privacy Officer at (312) 996-2271.

Right to Refuse to Sign this Authorization

You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in

this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

If you have not already received a copy of the Notice of Privacy Practices, you should ask for one.

Your signature below indicates that you are providing both consent to participate in the research study and authorization for the researcher to use and share your health information for the research.

What if I am a UIC student?

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

What if I am a UIC employee?

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC. You will not be offered or receive any special consideration if you participate in this research.

Remember:

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

- We, the researchers participating in this study, may want to use your research data for additional research related to pain in the future. If we use your research data we will not include your name or any other information that identifies you. If you do not want us to use your data for other studies, it will be destroyed 6 years after this study is completed.

  Do you agree to allow us to use your data for future studies (please circle YES or NO and initial next to your choice)?

  YES _____ NO _____

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

Signature	Date
Printed Name	
Signature of Person Obtaining Consent	Date (must be same as subject's)
Printed Name of Person Obtaining Consent	