IRB Approved: 10/25/2022
Approval Expires: 10/24/2023

OREGON HEALTH & SCIENCE UNIVERSITY

MED. REC. NO. _____
NAME _____
BIRTHDATE _____

IRB#: 18191

Clinical Research Consent Summary

Study Title: Remote Mindfulness-Education Intervention for Women with Provoked Localized Vulvodynia: A Randomized Clinical Trial

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. We do research studies to try to answer questions about how to treat conditions like vulvodynia.

We are asking you to take part in this research study because you have a specific vulvar pain condition called provoked localized vulvodynia (PLV) that causes painful sexual intercourse, among other symptoms.

Do I have to take part in this study?

Taking part in this study is your choice. You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered.

CO1450

Why is this study being done?

This study is being done to answer the following question:

Can an online program containing education or education and mindfulness exercises address the pain and psychosexual distress associated with provoked localized vulvodynia?

We are doing this study because we want to find out if this program can help ease the pain and psychosexual distress associated with PLV, which is often neglected by surgical and other non-surgical treatments for this condition. Both education seminars and education seminars combined with mindfulness therapy have been shown to reduce the pain and distress of PLV, but an online program has not be assessed. We hope to find out if an online program is also an effective method, since committing to multiple in-person sessions can be difficult for many individuals.

We are asking you to provide information for a data bank, also called a repository. This information will be stored indefinitely and may be used and disclosed in the future for research.

What is the usual approach to my provoked localized vulvodynia?
The usual approach for patients who are not in a study is treatment with surgery, physical therapy, medications such as lidocaine creams or nerve blocks and psychotherapy. Generally, a combination of these treatments are used. Your doctor can explain which treatment options may be best for you. These treatments can help you have less pain and distress.

Some people may also engage in information gathering or mindfulness practice on their own.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual treatments for your provoked localized vulvodynia.
- You may choose to take part in a different research study for this condition, if one is available.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will participate in either weekly online education seminars that involve engaging with reading materials and videos, or these weekly online education seminars combined with a daily 10-20 minute mindfulness meditation practice. Both of these interventions will last 8 weeks. You will have a 50/50 chance of being in either of the two groups. You can continue to receive your usual care for vulvodynia while participating in the study, which means you may continue to engage in physical therapy or take any medications that have been prescribed to you for this condition. You do not need to stop your care for this study.

If you decide to take part in this study, you will have the following procedures performed during the study:

- Surveys/questionnaires
- Self-directed education seminars (both groups)
- Daily mindfulness practice using Headspace© app (mindfulness group only)
- Tampon test

After you finish the 8 week online program, your investigator will continue to follow you for 6 months. You will receive emails with follow up questionnaires at 3 months and 6 months after you have completed the online program.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the “WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?” section.

If you choose to take part in this study, you will be answering questionnaires about sexual function and quality of life. There is a risk that these questionnaires may seem very personal or embarrassing.

Benefits

There is evidence that both education seminars alone and mindfulness practice + education seminars may be effective in easing pain and distress associated with vulvodynia. It is not possible to know how effective the online program will be at improving your pain and distress compared to other counseling approaches. This study will help the investigators learn things that will help people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let the investigator know as soon as possible. If you stop, you can decide if you want to keep letting the investigator know how you are doing.

The investigator will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The investigator may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by the Institutional Review Board (IRB), or investigator.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the investigator or study staff.

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Clinical Research Consent and Authorization Form

TITLE: Remote Mindfulness-Education for Women with Provoked Localized Vulvodynia: A Randomized Clinical Trial

PRINCIPAL INVESTIGATOR:	Catherine Leclair MD	(503) 494-2560
CO-INVESTIGATORS:	Katherine DeJong MD	(503) 494-2560
	Jessica Nikki Steinsiek	(503) 494-2560

WHO IS PAYING FOR THE STUDY? OHSU Resident Research Fund, Department of Obstetrics and Gynecology

WHY IS THIS STUDY BEING DONE?

You have been invited to be in this research study because you have a specific vulvar pain condition called Provoked Localized Vulvodynia (PLV)-previously known as *vulvar vestibulitis syndrome.* The most common symptom in women who have PLV is painful sexual intercourse. There are surgical and non-surgical treatments for this condition but many of these treatments neglect the anxiety, distress, depression and stress that can occur in women with this pain condition. This study is looking the effectiveness of an on-line remote program to treat the psychosexual distress associated with this condition.

The interventions we are studying are experimental. We do not know if they are better than the other approaches for treating PLV.

This study requires no visits to the clinic, although you may be consented during a CWH clinic visit if that is most convenient for you. The intervention sessions will last 8 weeks. You will also receive some follow up questionnaires 3 months and 6 months after the end of the interventions.

We are asking you to provide information for a data bank, also called a repository. This information will be stored indefinitely and may be used and disclosed in the future for research.

We hope to enroll approximately 40 individuals with PLV.

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WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?:

Screening and Consent

Your consent visit will either happen during a visit at the vulvar clinic in the Center for Women's Health or over the phone. During this visit, we will go over the consent form and you will decide if you wish to participate in the study. We will also review your medical history and physical exam that occurred during your most recent visit at the vulvar clinic to confirm that you have a diagnosis of provoked localized vulvodynia.

Once you have agreed to participate in the study, the following will happen prior to your eight week intervention:

- You will be randomized to either the education seminar group or the mindfulness practice + education seminar group
- You will fill out baseline questionnaires provided via email
- Baseline tampon insertion test (using provided standard tampons)
- Receive access to Box → secure virtual cloud where education seminars will be posted each week
- Receive access to HeadSpace© app **(if randomized to the mindfulness practice + education seminar group only)**

This is a randomized study. Neither you nor the investigator can choose whether you do the education seminars alone or in combination with the mindfulness practice. You will have a 50/50 chance of being in either of these two groups.

The baseline questionnaires ask you questions about your quality of life, mental health, sexual function, pain perception and other topics. You will fill these same questionnaires out again at the end of the study and at 3 months and 6 months of follow up. All questionnaires will be received via email and completed through an online secure survey system called RedCap.

Eight Week Intervention

During each week of the 8 week intervention you will engage with the following:

- Educational seminars
- 10-20 minutes of daily meditation practice using HeadSpace© app **(mindfulness + education seminar group only)**
- Weekly tampon insertion test
- Brief weekly survey asking about your engagement with the education materials
- Brief weekly survey asking about your engagement with mindfulness practice **(mindfulness + education seminar group only)**

The weekly survey should take you approximately 5 minutes to complete and will be sent to you via email. You will also receive a weekly text reminding you that new education materials have been posted.

At the end of the 8 week intervention, you will complete the same questionnaires that you completed during screening as well as an additional satisfaction questionnaire. You will also be asked to perform a tampon insertion test and rate your pain with insertion.

3 Month and 6 Month Follow Up

At 3 months and 6 months after your completion of the 8 week intervention, you will receive an email with a link to the study questionnaires. You will also be asked to perform a tampon insertion test and rate your pain with insertion.

In the future, your information may be given to researchers for other research studies. The information will be labeled as described in the **WHO WILL SEE MY PERSONAL INFORMATION?** section.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:

One risk to taking part in this study is that the study intervention you receive may not be effective in helping to treat your vulvodynia. This means you may spend time in the study that may not provide you with any health-related benefits.

Some of the questions about your quality of life, mental health and sexual function may seem very personal or embarrassing. They may upset you. You may refused to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.

WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?:
You may choose not to be in this study. You will still receive care from the Center for Women's Health and your healthcare provider. There are many options for other treatments for vulvodynia that you may try.

WHO WILL SEE MY PERSONAL INFORMATION?
We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. You will be given a unique study ID number, and all materials will be labeled with that coded identifier. Your initials, birth date, or other identifiers will not be used as part of the code. All information collected for this study will be digitally stored in a secure database called RedCap and can only be access by people who are working on the study.

We will create and collect health information about you as described in the WHY IS THIS STUDY BEING DONE? and the WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY? sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study and store in the Women's Health Research Unit Repository (eIRB# 6748) for future research.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including

- The Office for Human Research Protections, a federal agency that oversees research involving humans

Those listed above may also be permitted to review and copy your records, including your medical records.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

Under Oregon law, suspected child or elder abuse must be reported to appropriate authorities.

When we send information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your information could be used and re-released without your permission.

Data from this study may be shared with other investigators for future research studies. All identifying information about you will be removed from the samples before they are released to any other investigators.
We may continue to use and disclose your information as described above indefinitely.

Some of the information collected and created in this study may be placed in your OHSU medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT?

Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?:

There will be no cost to you or your insurance company to participate in this study.

If you have been randomized to the mindfulness practice + education seminar group, you will receive reimbursement for 2 months of access to the Headspace© app, or $26.

You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet.

We may request your social security number in order to process any payments for participation.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?:

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact the study investigator at 503-494-2560. You may also call the Center for Women's Health at 503-418-4500 or for after hours, you may call 503-494-8311.

If you are injured or harmed by the study sessions you will be treated. OHSU does not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

WHERE CAN I GET MORE INFORMATION?:

If you have any questions, concerns, or complaints regarding this study now or in the future, contact Catherine Leclair MD at 503-494-2560 or other members of the study team at 503-494-3666.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

DO I HAVE TO TAKE PART IN THIS STUDY?:

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join this study, or if you withdraw early from the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Catherine Leclair, MD
3181 SW Sam Jackson Park Rd, UHN-50
Portland, OR 97239
whru@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If you choose to withdraw from the study, there will be nothing further you need to complete. If in the future you decide you no longer want to participate in this research, we will remove your name and any other identifiers from your information, but the material will not be destroyed and we will continue to use it for research.

You may be removed from the study if you fail to complete your weekly assignments or do not respond to our contact attempts.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Subject Printed Name	Subject Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date