Novel web-based, self-directed intervention for chronic pelvic pain

NCT06352840

Date of IRB Approval: July 16, 2024

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:
Novel web-based, self-directed intervention for chronic pelvic pain

Company or agency sponsoring the study:
Health and Human Services Department of the National Institutes of Health

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Sara Till, MD, MPH, Obstetrics and Gynecology, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

Behavioral intervention study
This research study is evaluating whether behavioral changes, self-guided activities, or symptom monitoring results in improvement in chronic pelvic pain (CPP) symptoms and quality of life. In addition, the fact that this intervention is entirely online may decrease barriers that current limit access to these types of CPP treatment options, such as identifying specialists in your area or travel to medical appointments. Your health-related information will be obtained through review of your medical records, self-reported information that you provide through online questionnaires and will be collected for this research study.

This study involves a process called randomization. This means that the program you are assigned to in the study is not chosen by you or the researcher. The study design divides study participants into

separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

If you participate in this study, you will receive access to one of two different web-based pain self-management programs in addition to continuing care with your chronic pelvic pain provider. These self-guided programs are designed to help you manage your pelvic pain symptoms. The two different programs contain slightly different information, but you get to decide which of the tools or skills you want to use and how often you want to practice the skills or visit the website. You will not get to choose which of the two programs you will have access to but will be randomly placed into a program.

During the study period, you will continue to see your chronic pelvic pain provider and will have access to any treatment strategy that is recommended by your provider.

You will be asked to complete an online, comprehensive set of questionnaires at several time points during this study (baseline, 3-months, 6-months). Some patients may be invited to complete additional brief monthly virtual surveys about how they chose to use the web-based program in the prior month. Some patients may also be invited to participate in a virtual focus group at the 3-month time point to give more detailed feedback about their experience using the intervention. The focus group will be video and audio recorded.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include, feeling discomfort when answering personal questions about your health history and in the questionnaire, or experiencing symptoms of exacerbation. There is also a risk that you do not experience any improvement in your symptoms or condition as part of this study. Another risk may include having your personal information unintentionally disclosed. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by potentially improving your pain interference, physical function, and health-related self-efficacy. We also hope that this study will help us refine the program to best meet the needs of chronic pelvic pain patients in the future. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 7 months.

You can decide not to be in this study. Alternatives to joining this study include continuing clinical care with your chronic pelvic pain care team.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this intervention is to evaluate whether behavioral changes, self-guided activities, or symptom monitoring results in improvement in chronic pelvic pain (CPP) symptoms. In addition, this online intervention may decrease barriers that current limit patient access to these types of CPP treatment options. This study will provide patients with a web-based, self-management program that will help manage and cope with symptoms. We hope that patients with CPP will find a web based self-management program will improve pain, functions, and quality of life.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

We are recruiting women with chronic pelvic pain that last for at least 14 days of each month, who are patients of the Department of Obstetrics and Gynecology at the University of Michigan for treatment of chronic pelvic pain.

You may take part in this study if you are:

- Female sex assigned at birth (cis-female or trans-gender, nonbinary)
- Over the age of 18 years old
- Experience chronic pelvic pain that lasts for at least 14 days of each month
- A patient of the Department of Obstetrics and Gynecology at the University of Michigan for treatment of chronic pelvic pain

You may not participate in this study if you are/have:

- Do not have internet access
- Non-English speaking
- Had gynecologic surgery within the last 3 months
- Plan to have gynecologic surgery within the next 6 months
- Currently pregnant
- Severe physical impairment that will prevent you from participating in an internet-based program (for example, complete blindness or deafness)
- Current psychiatric disorder with history of psychosis (for example, schizophrenia, schizoaffective disorder, delusional disorder)
- Current suicidal ideation or suicide attempt within the last 2 years

We will screen for severe depression and suicidality at each questionnaire time point and have developed a robust triage and referral plan.

3.2 How many people are expected to take part in this study?

Up to 125 participants are expected to participate in this study. Participants will be randomized into two groups. Patients will be randomized to receive access to one of two different web-based pain self-management programs, in addition to usual care as determined by your chronic pelvic pain provider.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you participate in this study, you will receive access to one of two different web-based pain self-management programs in addition to continuing care with your chronic pelvic pain provider.
These self-guided programs are designed to help you manage your pelvic pain symptoms. The two different programs contain slightly different information, but you get to decide which of the tools or skills you want to use and how often you want to practice the skills or visit the website. You will not get to choose which of the two programs you will have access to but will be randomly placed into a program.

During the study period, you will continue to see your chronic pelvic pain provider and will have access to any treatment strategy that is recommended by your provider.

You will be asked to complete an online, comprehensive set of questionnaires at three time points during this study (baseline, 3-months, 6-months). Some patients may be invited to complete additional brief monthly virtual surveys about how they chose to use the web-based program in the prior month. Some patients may also be invited to participate in a virtual focus group at the 3-month time point to give more detailed feedback about their experience using the intervention.

4.2 How much of my time will be needed to take part in this study?

The web-based programs that you will have access to as part of this study are designed to be used on a regular basis, although you are able to decide how often and which parts of the program you choose to visit or use.

All participants will be asked to complete an online, comprehensive set of questionnaires at three time points during this study (baseline, 3-months, 6-months). We anticipate that it will take about 1.5-2 hours to complete all of the questionnaires at each time point. Some patients may be invited to complete additional brief monthly virtual surveys about how they chose to use the web-based program in the prior month. We anticipate that it will take less than 10 minutes to complete each of these surveys. Some patients may also be invited to participate in a virtual focus group at the 3-month time point to give more detailed feedback about their experience using the intervention. We anticipate that this virtual focus group will take about 1 hour.

You will continue to see your chronic pelvic pain provider as indicated and your participation in this study will not affect access to your provider.

4.3 When will my participation in the study be over?

The total amount of time that patients will actively participate in this study is approximately 7 months. Your participation in the study will end after you complete the 6-month questionnaire.

4.4 What will happen with my information and/or biospecimens used in this study?

Your collected information may be shared with the National Institute of Child and Maternal Health.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- *Discomfort associated with being asked personal questions about health history and the completion of questionnaires.* We will try to minimize these risks by allowing you to ask for clarification of any questions that you find to be unclear or troubling and allowing you to refuse to answer questions that you find too uncomfortable.
- *Symptom exacerbation (worsening):* We do not anticipate that these programs are likely to place you at an increased risk of symptom exacerbations (worsening). However, new treatments or activities sometimes cause a temporary increase in pain. This is a well-described phenomenon and is not unique to this program. We will try to minimize these risks by allowing you to decide how to use the program at your own pace. This program is not a replacement for professional medical advice, and you should contact your provider if you have urgent concerns. You can continue to access your chronic pelvic pain provider as needed and can initiate any new treatments recommended by them during this study period.
- *Depression exacerbation:* Patients with chronic pelvic pain have higher rates of depression compared to patients without chronic pain conditions. While we do not anticipate that these programs are likely to worsen symptoms of depression, we want to ensure that patients who are suffering from severe depression receive appropriate treatment. The researchers will try to minimize these risks by scoring the depression questionnaire immediately. If a patient receives a score > 70, consistent with severe depression, they will receive a call from a study member who will complete a brief screen for suicidal ideation. If positive, the patient will be referred to the University of Michigan Psychiatric Emergency Service. If no suicidal ideation, we will offer referral to University of Michigan Depression Center or offer to contact the patient's PCP to help facilitate evaluation and treatment.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still experience worsening symptom, even when we are careful to avoid them. Please contact us with the contact methods in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
Based on data from similar studies in patients with other chronic pain conditions, we anticipate that patients may see improvements in pain, function, and quality of life by participating in this program. However, it is possible that you may not experience any symptom improvement or benefit from being in this study.

We also anticipate that the information gathered from this study will allow us to refine the program to best meet the needs of similar patients with chronic pelvic pain. It is possible that other people with chronic pelvic pain may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Your participation in this study is completely voluntary. You will maintain the same access and follow up with your chronic pelvic pain provider whether or not you choose to participate in this study. You can choose to begin any treatment or medication, or undergo surgery as recommended, regardless of whether you choose to participate in this study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
We do not anticipate that leaving the study before it is finished is likely to cause any harm to you, but it is possible that you may experience less symptom improvement if you leave before study completion.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- You do not follow instructions from the researchers.

- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill, you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

All patients will be asked to complete an online, comprehensive set of questionnaires at three time points during this study (baseline, 3-months, 6-months). You will receive $50 after you complete questionnaires at each of the three time points.

Some patients may be invited to complete additional brief monthly virtual surveys about how they chose to use the web-based program in the prior month and will receive $5 after completing each of these surveys. Some patients may also be invited to participate in a virtual focus group at the 3-month time point to give more detailed feedback about their experience using the intervention and will receive $100 after participating in the focus group.

8.3 Who could profit or financially benefit from the study results?

The researchers conducting the study: The researchers have created a website for this program in partnership with the University of Michigan, which is freely and publicly available. The researchers do not receive any revenue or financial benefit related to this website.

The University of Michigan: Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Paper copies of the screening worksheet to assess study eligibility will be stored in a locked cabinet and will not be made part of your electronic medical record. All additional study-related documents will be collected electronically, including a signed copy of this consent form and all online questionnaires, and none of these documents will be part of your electronic medical record. Signed consent forms will be stored on a University of Michigan secure drive. All questionnaire data will be entered into Qualtrics, apassword protected, 21 CFR Part 11-compliant data capture system provided by the University of Michigan. All paper and electronic study documents will be retained for a minimum of three years after study completion.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Child Health and Human Development (NICHD) which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. 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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Sara Till, MD, MPH
Mailing Address: 1500 E. Medical Center Dr. Ann Arbor, MI 48109
Telephone: 734-232-1333

Study Coordinator: Jordyn Boggan
Mailing Address: 1500 E. Medical Center Dr. Ann Arbor, MI 48109
Telephone:

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road

Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

You ***will receive a copy of the signed and dated informed consent***.

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with a study team member. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to participate in Focus Group for this study.
This project involves the option to participant in an online discussion group where participants can express their likes or dislikes about the program. I understand that it is my choice whether to participate in this discussion. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this focus group.

_____ Yes, I agree to participate in the focus group for this study.

_____ No, I do not agree to participate in the focus group for this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to video/audio recording solely for purposes of the focus group
This study involves video and/or audio recording for the focus group. If you do not agree to be recorded, you can still take part in the overall study, but not the focus group.

_____ Yes, I agree to be video/audio recorded for the focus group.

_____ No, I do not agree to be video/audio recorded for the focus group.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____