Exploring Patient Treatment Preferences for Chronic Pelvic Pain: A Mixed Methods Study

NCT06540560

Date of IRB Approval: July 8, 2024

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Exploring Patient Treatment Preferences for Chronic Pelvic Pain: A Mixed Methods Study

Company or agency sponsoring the study: National Institutes of Health

Principal Investigator: Sara Till, MD, MPH

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 these matters carefully.

We are doing this study to learn about how people feel about various treatments for chronic pelvic pain. We are also interested in whether a web-based educational and self-management program for chronic pelvic pain changes how people think about chronic pelvic pain treatments. Participants will complete a survey and an individual interview. Then participants will receive access to the web-based program for two weeks. This program contains several different self-guided modules that include cognitive and behavioral structuring, self-administration of acupressure, engaging in physical activity, and a brief introduction to pelvic floor physical therapy techniques. After the two weeks, participants will complete another survey.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. Participation in this study may involve rare risks, including breach of confidentiality, discomfort with being asked personal questions about health history and survey completion, and symptom exacerbation. We make every effort to minimize these risks. We protect your data and confidentiality by only allowing study staff access to your data and practicing security measures for your data. You are allowed to withdraw from the study at any time. Finally, we do not expect the program to increase your symptoms. 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 improving your pain interference, physical function, and health-related self-efficacy. We also anticipate that the information from this study will allow us to improve treatments for chronic pelvic pain. More information will be provided later in this document.

We expect that you will be receiving study interventions and study follow-up for four weeks.

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 research study is to find out what affects the way people think about different ways to treat chronic pelvic pain. We also want to see if using a new online program that teaches people about pelvic pain and how to manage it can make people more open to trying different treatments or believe more in the treatments they're given.

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?

Women who are at least 18 years old, have English-language proficiency, have chronic pelvic pain and are scheduled for a new patient visit with the Chronic Pelvic Pain and Endometriosis Referral Clinic within the Department of OBGYN at the University of Michigan.

Participants must have access to the internet.

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

30 women will be enrolled in this study

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Participants will complete a survey asking about demographics, pain symptoms, quality of life, pelvic pain diagnoses, and previous treatments for pelvic pain symptoms. Then participants will be asked to complete an individual interview. The interview will focus on history of interactions with medical providers, preferred sources of medical information, your opinions about different treatments, and prior experience with different treatments. Then participants will receive access to the web-based program for two weeks. This program contains several different self-guided modules that include cognitive and behavioral structuring, self-administration of acupressure, engaging in physical activity, and a brief introduction to pelvic floor physical therapy techniques. After the two weeks, participants will complete another survey which will include questions about willingness to try different treatments, your opinions on different treatments, and your self-efficacy for managing symptoms.

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

The first surveywill take about 25 minutes. The interview will take about 30 minutes. The second survey will take about 10 minutes. Participants can spend as much or as little time in the web-based program as they would like.

4.3 When will my participation in the study be over?

Your participation in the study will last approximately four weeks, and will be over after you complete the second survey.

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:

- breach of confidentiality,
- discomfort associated with being asked personal questions about health history and the completion of questionnaires, and
- symptom exacerbation.

The researchers will try to minimize these risks by:

- Several measures have been taken to reduce the risk of breach of confidentiality. These include training of study team members, electronic and physical security measures for data capture and storage and collecting a minimum of identifiable information for each individual project. Any security breaches will be reported to the University of Michigan Institutional Review Board, as required.
- Any participant becoming distressed while completing questionnaires will be encouraged to seek clarification of any questions that they find to be unclear or troubling. All participants are told that they have the option to terminate participation without penalty and/or will be assisted in arranging medical/ psychiatric help including, if necessary, emergency treatment if needed.
- We do not anticipate that the My Pelvic Plan program is likely to place patients at an increased risk of symptom exacerbations. Cognitive and behavioral programs have been shown to be low risk for adverse events.

As stated above, there may be a risk involving loss of confidentiality or privacy. For example, if individuals outside this study were to discover that you were a participant in this research, or if any collected identifiable genetic or health information were disclosed to unauthorized persons, there is a risk of discrimination by employers or insurance providers. The researchers have adopted privacy and confidentiality procedures to help prevent such disclosures. 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.

Keep in mind, as well, that the committee (IRBMED) that reviews this study does not review risks associated with procedures that are conducted as part of your regular medical care and are not part of the research, including those marked "[Not research]" in section 4.1, above. Risks associated with your regular medical treatment should be discussed with your regular doctor.

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 have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors or any other provider or hospital you visit**.**

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?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

Based on data from similar interventions in patients with other chronic pain conditions, we anticipate that patients who utilize the web-based self-management program may see modest improvement in pain interference, physical function, and health-related self-efficacy associated with participation in this study (immediate and short-term potential benefits).

We also anticipate that the information gathered from this study will allow us to improve patient-centered counseling and shared decision making to better meet the needs of similar patients with chronic pelvic pain.

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?

Tell us if you are thinking about stopping or decide to stop. It is important to tell us if you are thinking about stopping so any risks can be evaluated by the researchers. We will also tell you how to stop safely and discuss what follow-up care and testing could be most helpful for you. If you decide to leave the study before it is finished, please tell one of the researchers listed in Section 10 “Contact Information” (below).

You are free to end your participation partially or completely in the study. An example of partially ending your participation would be to discontinue receiving study intervention, while still allowing continuation of study follow-up procedures.

Please note that any information collected before you withdraw will be kept and used to complete the research.

Please note that even if you withdraw consent for further follow-up or contacts, if the study doctor becomes aware of additional safety information this will be reported to the sponsor to comply with legal or regulatory requirements.

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 researchers believe that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- 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. The procedures described in section 4.1 may include some non-research procedures. Those designated as “[Not research]” will not be paid for by the study. If you are not sure which procedures or services the study will pay for, 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.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

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

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

All patients will receive $25 for completion of each of the questionnaires and $50 for completion of the individual structured interview. Therefore, patients who complete all portions of the study will receive a total of $100. Of note, patients will also retain access to the web-based self-management program as part of their study participation.

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

The researchers do not profit or financially benefit from the study results.

The University of Michigan is receiving payments from the National Institutes of Health to support the activities that are required to conduct the study.

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 PARTICIPANT 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?

Your participation will occur at Michigan Medicine. Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:

- Your name will not be used in any reports about the study
- You will be identified only by a study code
- Your identifying information will be kept secure

Despite these protections, some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., initials, date of birth).

Your research information will be stored in locked cabinets and offices. Your research information will be stored electronically in encrypted, password-protected secure laptops wherein only research study team members have individual IDs and passwords to access the information. All electronic records are protected by network restrictions and security software. It will also be stored on the cloud; the term "cloud" refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files.

Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards. Only members of the study team will have access to your study information.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. We may also share your information with other researchers.
- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse and of some communicable diseases.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA).
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://www.era.nih.gov/erahelp/CoC_Ext/Content/A-Introduction/Introduction.htm

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website 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 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 and for quality improvement purposes.
- 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 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 Michigan Medicine medical record.
- If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.
- 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

If 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 does not expire unless you cancel it. 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
Email: OBGYNPelvicPain@med.umich.edu; jboggan@med.umich.edu

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?

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

Your signature in the next section means that you have received a copy of the following document(s):

- 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.)*

12. STORAGE, USE, AND SHARING OF SPECIMENS AND INFORMATION COLLECTED OR GENERATED IN THE STUDY DESCRIBED ABOVE

12.1 What is meant by the storage, future research use, and sharing of study participants' medical information and leftover samples (sometimes referred to as biospecimens) taken from me?

Individual researchers, the University of Michigan, and companies that design and sponsor studies often want to keep subjects' medical information to use in future research. These future research uses take different basic forms, which are described below. The medical information and leftover samples may also be shared with other researchers so that they can use it in their studies.

The purpose of storing, using, and sharing participants' medical information and leftover samples is to promote more research that might lead to useful medical discoveries.

In some cases, researchers need your consent to store, use, and share your medical information and leftover samples; in other cases, they can store, use and/or share it without your consent. Whether or not researchers need your consent depends on if the stored information and samples would still be identifiable as yours or whether the researchers would first remove all information connecting them back to you.

12.2 Types of storage, future research use, and sharing in this study

For purposes of this research study, your collected private information and any biospecimens will be shared with the study sponsor, the National Institutes of Health, its collaborators, and associated research partners.

In addition, after identifiers are removed from your private information and any biospecimens, the information and biospecimens could be used for future research studies by U-M and shared with other researchers or companies, including those in other countries, without your additional informed consent.

In each of the situations described below, you may later change your mind and withdraw your consent to the storage, use, and sharing of your information even if you give consent now, provided that the information can still be identified as yours, has not already been used or shared, or has not been added to your medical record. Keep in mind, however, that any information that has already been used or shared with other researchers, as well as any information that has been added to your medical record, cannot be recovered, or deleted.

We will assign your information a random code, rather than your name or any other details that others could use to identify you, before sharing it with other researchers. The principal investigator will securely store the code key that links your coded information to you.

Researchers who wish to access your information must obtain permission to access your information.

Permitting us to store and share your information is a condition of participating in this study. If you do not want us to share your information with other researchers, you should not take part in this study.

13. SIGNATURES

Consent/Assent 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 member of the study team. 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): _____

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): _____