Optimizing Psychosocial Treatment of Interstitial Cystitis/Bladder Pain Syndrome
IRB Approval 6/22/2021
NCT #NCT04275297

Econsent Part 1

Hi! This is Gracie from the Interstitial Cystitis study. Please click below to reach the surveys we discussed over the phone. Thank you for being a part of this study.

1) Name of participant: _____

2) Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key information about this study:

You are being asked to participate in this research study as a patient with interstitial cystitis/bladder pain syndrome. The purpose of this research study is to examine treatments for interstitial cystitis and to learn about different presentations of the condition. The study involves a series of three assessment visits, and 8 additional weekly visits that will occur either over the phone, online, or in person at a VUMC outpatient clinic. This study will help us learn about different symptom presentations of interstitial cystitis, and how treatment may help improve symptoms. If successful, the treatment offered in this study could be used much more widely across the country.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Procedures to be followed and approximate duration of the study:

If you choose to participate in this study, you will be asked to complete three assessment visits, and then engage in a series of either 8 weekly telephone calls or 8 weekly in-person or teleconferencing visits. The three assessment visits will occur once before, immediately after, and then three months following your 8 weekly appointments. The duration of the study will be approximately five months. Each assessment visit will have two stages, Stage 1 (questionnaires) and Stage 2 (in-person assessment).
This consent form applies to Stage 1 of the assessments.

Each Stage 1 assessment visit will take between 30-45 minutes. During each assessment visit, you will complete questionnaires that can be taken 1) online, or 2) via computer on site at VUMC.

After your first assessment visit, you will be scheduled to have either 8 weekly phone calls or 8 in person or teleconferencing visits. The phone calls will occur one week apart and are designed to monitor your symptoms. Each week, we will ask about your symptoms, flare patterns, and questions about your physical and emotional wellbeing. The in-person or teleconferencing visits will involve an 8-week self-management program for interstitial cystitis designed to learn different skills to manage and cope with urinary symptoms and pain. Each visit will occur with OCIM either online or in person and last approximately 50 minutes. If enrolled in this group, you will likely be asked to complete homework between appointments to practice what you learn during the program.

Expected costs:

The visits and assessments are provided at no cost. They will not be billed to insurance. Expected costs may involve time and travel to appointments similar to when you visit the doctor. If you are driving a long distance outside of Davidson County you may be eligible for travel reimbursement and can speak with study investigators about this.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

In speaking with a provider over the phone about your symptoms, you may find this mildly distressing at times. Just like with the questionnaires during your assessment visits, you do not have to answer any questions you do not wish to answer. Similarly, if you meet with a provider in person to engage in the self-management program, working to understand and cope with symptoms in a new way could cause mild discomfort. This is natural to the change process. You will work with a trained professional who has your best interests in mind and will work with you at a pace that you agree on, which feels comfortable to you. Your practice of new skills learned is encouraged, but entirely your choice.

Unforeseeable risks:

Because this treatment is investigational, meaning not yet "evidence-based," there may be unknown or unforeseeable risks associated with participation.

Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator [with Sponsor input] that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury. There are no plans for Vanderbilt [or the Sponsor] to pay for any injury caused by the usual care you would normally receive for treating your illness or the cost of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury.

Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study.

The potential benefits of this study are to assist in providing an evidence base for this specialized service, potentially widening access to this service through further dissemination, education, and training to make it accessible to more patients with interstitial cystitis. In addition, participation in this study could provide new information about different symptom presentations and how psychosocial self-management programs for Interstitial Cystitis/Bladder Pain Syndrome impact health and wellbeing for patients across the spectrum of illness.

b) The benefits you might get from being in this study.

There may be no direct benefit from participating in this study. However, you may find the intervention to be beneficial to your state of mind and your symptom experiencing.

Can I continue whatever treatment/management I am already doing?

Yes, this trial does not require you to stop any other treatment you may already be implementing. It is designed to complement your current regimen. We do ask that during the 5-month period of the study, you do not start any additional treatment that could affect your mental health or IC symptoms, such as psychotherapy in the community, starting a new drug, or undergoing new procedures that are not already a part of your regular treatment plan. If you currently take pain medicines, you may be asked to not take them the morning of your assessment visit until completing this visit. If you have recently had a change to any of your medicines, we may delay your enrollment in the study until you are considered stabilized on the medicine.

Alternative treatments available:

Self-management programs involve working with a trained mental health provider on addressing symptoms and coping with interstitial cystitis. If you wish to seek additional mental health care elsewhere we will be happy to provide you with referrals in the community.

Compensation for participation:

You will be compensated $40.00 for each of the three assessment visits for up to a total of $120.00. Depending on your distance traveling to appointments and needs, we may be able to provide compensation for travel mileage.

Circumstances under which the Principal Investigator may withdraw you from study participation:

Although unlikely, the Principal Investigator may withdraw you from the study if you are determined to have certain conditions that may interfere with the accuracy of test results or treatment response. We check for this information prior to offering you the opportunity to participate in this research, and this would happen only in the rare circumstance that this information had been missed, recorded incorrectly, or changes after the screening process. This will not affect compensation for your participation to-date.

What happens if you choose to withdraw from study participation?

If you decide to stop being part of the study, you should inform Dr. McKernan at (615) 875-9990. Deciding to not be part of the study will not change your regular medical care or relationship with Vanderbilt University Medical Center in any way.

Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact Lindsey C. McKernan, Ph.D. at (615) 875-9990.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Records related to the study will be stored and maintained on-site via computer and secured at all times by Dr. McKernan and her research team. Dr. McKernan will store protected health information and/or identifying information in a separate database, assign a number to your responses, and have a key to indicate which number belongs to which participant accessed only by Dr. McKernan and one other member of the research team. Dr. McKernan is also requesting permission to contact you to potentially offer participation in future research studies. Any articles or presentations that result from this research will heavily disguise or conceal personal information to maintain confidentiality.

If you engage in the self-management program, your visits will be audio recorded by the provider you are working with. A percentage of these will be reviewed by Dr. McKernan. This is done to make sure the practitioner you are working with follows procedures. Once recordings are reviewed, they are destroyed.

During the research, if we learn you are having unmanageable thoughts about suicide or hurting yourself or others, the research staff or provider will ask you more questions about your thoughts. Based on your response, the staff may provide you with help to get treatment in the same way you would during a medical visit. This may include:
•,working with you to contact your doctor,
•,contact a trusted family member, or a therapist to discuss your thoughts,
•,or work with you on a plan that may include getting you to a hospital for safety

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Privacy of Protected Health Information:

As a part of this study, if you are being treated at Vanderbilt University Medical Center (VUMC), we are asking for permission to access your VUMC medical record for review. From your medical record, we will be gathering information related to current medication usage, diagnosis, treatment history, and your healthcare usage over the past 24 months. All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare.

This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below. As part of the study, Dr. McKernan and her study team may share the results of your study and/or non- study linked medical information, questionnaire results, healthcare utilization, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, the National Institute of Health, or other potential sponsors to support future studies. In addition, off-site collaborators at regional universities (e.g. University of Michigan Medical School) may have access to a limited data set resulting from this study, which uses PHI without direct identifiers. These individuals will have signed formal Data Use Agreements with Vanderbilt in compliance with HIPAA and the HITECH Act. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The sponsor and/or Vanderbilt may give your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr. McKernan and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

The study results will be kept in your research record for at least five years after the study is finished. At that time, the research data will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. McKernan in writing and let her know that you withdraw your consent. Her mailing address is [redacted] , Nashville, TN 37203. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

3) Date: _____

4) Signature of participant: _____

5) Consent obtained by (to be filled out by research staff): _____

6) Printed Name and Title (to be filled out by research staff): _____

Date of IRB Approval: 06/22/2021

Institutional Review Board

VANDERBILT

7) Date (to be filled out by research staff): _____

Econsent Part 1

Hi! This is Gracie from the Interstitial Cystitis study. Please click below to reach the surveys we discussed over the phone. Thank you for being a part of this study.

1) Name of participant: _____

2) Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key information about this study:

You are being asked to participate in this research study as a patient with interstitial cystitis/bladder pain syndrome. The purpose of this research study is to examine treatments for interstitial cystitis and to learn about different presentations of the condition. The study involves a series of three assessment visits, and 8 additional weekly visits that will occur either over the phone, online, or in person at a VUMC outpatient clinic. This study will help us learn about different symptom presentations of interstitial cystitis, and how treatment may help improve symptoms. If successful, the treatment offered in this study could be used much more widely across the country.

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Procedures to be followed and approximate duration of the study:

If you choose to participate in this study, you will be asked to complete three assessment visits, and then engage in a series of either 8 weekly telephone calls or 8 weekly in-person or teleconferencing visits. The three assessment visits will occur once before, immediately after, and then three months following your 8 weekly appointments. The duration of the study will be approximately five months. Each assessment visit will have two stages, Stage 1 (questionnaires) and Stage 2 (in-person assessment).
This consent form applies to Stage 1 of the assessments.

Each Stage 1 assessment visit will take between 30-45 minutes. During each assessment visit, you will complete questionnaires that can be taken 1) online, or 2) via computer on site at VUMC.

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Expected costs:

The visits and assessments are provided at no cost. They will not be billed to insurance. Expected costs may involve time and travel to appointments similar to when you visit the doctor. If you are driving a long distance outside of Davidson County you may be eligible for travel reimbursement and can speak with study investigators about this.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

In speaking with a provider over the phone about your symptoms, you may find this mildly distressing at times. Just like with the questionnaires during your assessment visits, you do not have to answer any questions you do not wish to answer. Similarly, if you meet with a provider in person to engage in the self-management program, working to understand and cope with symptoms in a new way could cause mild discomfort. This is natural to the change process. You will work with a trained professional who has your best interests in mind and will work with you at a pace that you agree on, which feels comfortable to you. Your practice of new skills learned is encouraged, but entirely your choice.

Unforeseeable risks:

Because this treatment is investigational, meaning not yet "evidence-based," there may be unknown or unforeseeable risks associated with participation.

Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator [with Sponsor input] that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury. There are no plans for Vanderbilt [or the Sponsor] to pay for any injury caused by the usual care you would normally receive for treating your illness or the cost of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury.

Good effects that might result from this study:

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Can I continue whatever treatment/management I am already doing?

Yes, this trial does not require you to stop any other treatment you may already be implementing. It is designed to complement your current regimen. We do ask that during the 5-month period of the study, you do not start any additional treatment that could affect your mental health or IC symptoms, such as psychotherapy in the community, starting a new drug, or undergoing new procedures that are not already a part of your regular treatment plan. If you currently take pain medicines, you may be asked to not take them the morning of your assessment visit until completing this visit. If you have recently had a change to any of your medicines, we may delay your enrollment in the study until you are considered stabilized on the medicine.

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Circumstances under which the Principal Investigator may withdraw you from study participation:

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What happens if you choose to withdraw from study participation?

If you decide to stop being part of the study, you should inform Dr. McKernan at (615) 875-9990. Deciding to not be part of the study will not change your regular medical care or relationship with Vanderbilt University Medical Center in any way.

Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact Lindsey C. McKernan, Ph.D. at (615) 875-9990.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Records related to the study will be stored and maintained on-site via computer and secured at all times by Dr. McKernan and her research team. Dr. McKernan will store protected health information and/or identifying information in a separate database, assign a number to your responses, and have a key to indicate which number belongs to which participant accessed only by Dr. McKernan and one other member of the research team. Dr. McKernan is also requesting permission to contact you to potentially offer participation in future research studies. Any articles or presentations that result from this research will heavily disguise or conceal personal information to maintain confidentiality.

If you engage in the self-management program, your visits will be audio recorded by the provider you are working with. A percentage of these will be reviewed by Dr. McKernan. This is done to make sure the practitioner you are working with follows procedures. Once recordings are reviewed, they are destroyed.

During the research, if we learn you are having unmanageable thoughts about suicide or hurting yourself or others, the research staff or provider will ask you more questions about your thoughts. Based on your response, the staff may provide you with help to get treatment in the same way you would during a medical visit. This may include:
•,working with you to contact your doctor,
•,contact a trusted family member, or a therapist to discuss your thoughts,
•,or work with you on a plan that may include getting you to a hospital for safety

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Privacy of Protected Health Information:

As a part of this study, if you are being treated at Vanderbilt University Medical Center (VUMC), we are asking for permission to access your VUMC medical record for review. From your medical record, we will be gathering information related to current medication usage, diagnosis, treatment history, and your healthcare usage over the past 24 months. All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare.

This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below. As part of the study, Dr. McKernan and her study team may share the results of your study and/or non- study linked medical information, questionnaire results, healthcare utilization, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, the National Institute of Health, or other potential sponsors to support future studies. In addition, off-site collaborators at regional universities (e.g. University of Michigan Medical School) may have access to a limited data set resulting from this study, which uses PHI without direct identifiers. These individuals will have signed formal Data Use Agreements with Vanderbilt in compliance with HIPAA and the HITECH Act. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The sponsor and/or Vanderbilt may give your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr. McKernan and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

The study results will be kept in your research record for at least five years after the study is finished. At that time, the research data will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. McKernan in writing and let her know that you withdraw your consent. Her mailing address is [redacted] , Nashville, TN 37203. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

3) Date: _____

4) Signature of participant: _____

5) Consent obtained by (to be filled out by research staff): _____

6) Printed Name and Title (to be filled out by research staff): _____

Date of IRB Approval: 06/22/2021

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7) Date (to be filled out by research staff): _____