The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

MYPAICE: Mindfulness and Yoga for Pain with Interstitial Cystitis Evaluation

Dear Prospective Participant,

Dr. Kate Meriwether and her colleagues, from the UNM Department of Obstetrics and Gynecology, are conducting a research study. The purpose of this study is to examine the impact of doing meditation and yoga each day on pain levels and ability to do daily activities in woman who have Interstitial Cystitis/Painful Bladder Syndrome (IC/PBS). We will have up to 120 women participate in this study. This study is voluntary, and if you decide not to there will be no effect to your care.

If you are in this study, you will be told which group you are in for treatment. Which group you are in is decided at random (by chance), and will be either a group that will use simple, over-the-counter or lifestyle treatments for IC/PBS or will use these treatments IN ADDITION TO daily meditation and yoga using the Calm App. . If you are assigned to the group that does yoga and meditation, meditation will be performed via a Smartphone App, and a certified yoga instructor will send you a series of yoga poses. If you are in the group that just uses simple, over the counter or lifestyle treatments at the end of the study you are eligible for 3 months of the Calm App as well as access to the online yoga videos.

Both groups will have weekly check-ins over the phone or on Zoom with a research staff member to see how you are doing. This study will be performed using phone, Zoom, and email, so you don't have to come into clinics or see the research staff in person unless your doctor/provider asks you to come in person for treatments. This is to minimize concern for COVID-19 infection during this time. You will be in the study for 3-4 months total. Six weeks after the start of the study, you will have the opportunity to add additional treatments for your IC/BPS, and your doctor(s) will find the treatments that are best for you. As part of the study, we will be tracking what treatments you add.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you are assigned to either group, you may benefit from the greater attention with weekly check-ins. If you are assigned to the yoga and meditation group, you will receive 1) a video that will instruct you on use of yoga to help with IC/BPS symptoms (designed by a physical therapist who specializes in caring for IC/BPS patients) and 2) you will be able to use a meditation app (Calm App). (if you choose to have us sign up for it for you) for 3 months (the study will pay for it for that length of time). You might notice more relief from your IC/BPS symptoms if yoga and meditation improve IC/BPS. There is also the chance that there will be no benefit to you from taking part in this research study. However, being in the study may help us know how to better treat IC/BPS and help us improve the lives of patients with IC/BPS in the future.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There are no serious risks to mindfulness or yoga. You may have minor muscle aches with increased moving with yoga if you are in the yoga/meditation group. You are being asked to participate in this study because you:

- Are a woman at least 18 years old
- Have a diagnosis of IC/BPS based on a symptom questionnaire you will be given to determine your ability to participate in the study
- Speak and read/write either English or Spanish
- Have internet access or the ability to use Smartphone applications

If you qualify for this study, you will being asked to participate in an approximately 30-minute introductory session with our research team, where we will go over which group you are in and what instructions you should follow. If you are in the group that uses yoga and meditation, we will go over how to do the meditation on your cell phone and how to do the online yoga, so that you are comfortable using this. If you are in the group that uses yoga and meditation, we will ask you to keep track of how often you are doing yoga and meditation. All of these interventions are free to you.

If you are in the study, we will ask you to answer a set of questions at the beginning of the study, which will be done online through a computer program called Redcap. Answering these questions should take up to 30 minutes. The questions will include questions such as, "How much pain do you have on a scale of 0-10?" It is your choice to be in this study or not be in this study, and will not affect what sort of care you get for your IC/BPS. Due to COVID-19 and in an effort to protect everyone's safety, this study will all be done over the telephone or computer, so it can be done from your home. There will be no cost for travel or need to purchase anything to be in this study. Information that could allow other people to know you are in this study may include your name on contact information questions. All information about you will be kept for 5 years after the study is finished. This information will be kept in a locked cabinet in the OBGYN research office and then destroyed after 5 years. If results of this study are published (such as in medical journals or online), results will be presented in a way that will protect your privacy and not give away that you were part of this trial. More information about this study is available at ClinicalTrials.gov, If any novel findings come up during the study period, we may reach out to you to inform you of this.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI).

As part of this study, we will be collecting health information about you and sharing it with others. This information is "protected" because it is identifiable or "linked" to you. There is minimal risk to loss of confidentiality.

Protected Health Information (PHI)

By participating in this study, as described in this consent form, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information includes your name, date of birth, medical record number and telephone number for site use only and to ensure follow up.

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization or participation in the study at any time provided you notify the UNM investigators in writing. We will not terminate you from the study. To do this, please send letter notifying them of your withdrawal to:

Kate Meriwether, MD
Department of OB/GYN - Research
MSC10 5580
1 University of New Mexico
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before the date that your withdrawal is received. We may call you to determine your reason for leaving. If you have any questions about this research project, please feel free to call Dr. Kate Meriwether at (505) 967-8428. If you have questions about your legal rights as a research subject please call the UNM Human Research Protections Office at (505) 272-1129.

By participating in this research assignment, you will be agreeing to participate in the above described research study. You will receive a total of $60 in merchandise cards for your participation. You will receive $10 at enrollment and $50 at your 3-month follow-up visit. Thank you so much for your consideration.

Sincerely,

Kate Meriwether, MD
Assistant Professor

Department of Obstetrics and Gynecology
University of New Mexico