Study title: Smartphone-based Self-care Education Program for Women With Interstitial Cystitis: Educational Remote IC Aide

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UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Text message-based self-management program for women with interstitial cystitis/bladder pain syndrome
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Research Study Summary for Participants
You are being invited to participate in this research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the University of Pennsylvania Institutional Review Board (IRB) at PROVOST-IRB@pobox.upenn.edu or 215-898-2614.

The research study is being conducted to develop and test a text message-based program for self-management of Interstitial Cystitis/Painful Bladder Syndrome (IC/BPS) at home. Your total participation in the study will last for 6 weeks. First, you will participate in a phone or video conference (your preference) interview with a study member to tell us about your experience with IC/BPS and challenges you faced in seeking treatment for IC/BPS, and complete a set of questionnaires online. Then you will participate in a texting program for 6 weeks during which you will received treatment recommendations. At the end of each week, you will be asked about your symptoms. At the completion of the program, you will again participate in a phone or video conference interview and fill out a set of questionnatires.

By participating in the study, we hope that you learn valuable information on how to self-manage your IC/BPS symptoms. In addition, your feedback will help us refine the program and help other women who live with IC/BPS. While the risks of participation are minimal, you may discontinue your participation at any time if you are uncomfortable with sharing your experiences with IC/BPS. Your comments during the interviews are completely confidential.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?
You are being invited to participate in a research study because you have been diagnosed with IC/BPS.

If you decide to participate, you will be asked to sign this form.

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

What is the purpose of the study?
The purpose of the study is to develop and test a text message-based IC/BPS self-management program.

Why was I asked to participate in the study?
You are being asked to join this study because a physician has diagnosed you with IC/BPS and expressed potential interest in participating in this program.

How long will I be in the study?
Your participation will be for the duration of 6 weeks.

Where will the study take place?
You will be given a web link to a video conferencing platform (such as Zoom® or BlueJeans®) so that you can participate in a socially-distanced way for the interviews. You may also choose to have this interview over the phone. You can send and receive text messages from us from wherever you are. You will complete questionnaires either in person or remotely via REDcap which is a secure HIPAA compliant program.

What will I be asked to do?
Your total participation in the study will last for 6 weeks. First you will participate in an interview with a study member and complete a set of questionnaires. Then you will participate in a texting program for 6 weeks during which we will receive treatment recommendations and receive weekly check-ins. At the completion of the program, you will again participate in an interview and fill out a set of questionnatires that will take one hour to complete.

What are the risks?
There are very minimal risks to participation. If you are at all uncomfortable with sharing your experiences via text messages, you may discontinue your participation at any time.

How will I benefit from the study?
There may be a personal benefit in that you will learn how to self-manage your IC/BPS symptoms through this study. In addition, your participation and feedback could help us refine this program, which can eventually help other women with IC/BPS.

What other choices do I have?
You can choose not to participate in this study.

What happens if I do not choose to join the research study?
You may choose to join the study or you may choose not to join the study. Your participation is voluntary.

There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your doctor or other health care provider will not be upset with your decision.

If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

When is the study over? Can I leave the study before it ends?
The study is expected to end after all interviews and questionnaires have been completed. The study may be stopped without your consent for the following reasons:

- The principal investigator believes that it is best for your safety and/or health - You will be informed of the reasons why.
- You have not followed the study instructions
- The principal investigator, the sponsor or the Institutional Review Board (IRB) at the University of Pennsylvania can stop the study anytime

To reiterate, you have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care.

If you no longer wish to be in the research study, please contact Dr. Edward Kim at edward.kim@pennmedicine.upenn.edu or 215-439-5257.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will **not** be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

Confidentiality will be maintained throughout the study. We will **not** share your name or any identifiable personal health information during the discussion or as part of any research manuscripts that may come out of this study.

An exception to confidentiality is if you report child or elder abuse or neglect, or if you report suicidal or homicidal ideation or intent to the research team. Any information about child or elder abuse or intent to harm yourself or others will be reported to the authorities, as required by law.

What may happen to my information collected on this study?
We will transcribe the interviews, however we will **not** identify you in the transcript.
Regarding the questionnaires that you will be asked to complete, all of your information will be de-identified.

Future Use of Data
Your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. It would **not** be possible for future researchers to identify you as we would **not** share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

Will I have to pay for anything?
You will not have to pay for anything directly related to the study. You will be responsible for any costs associated with sending and receiving text messages.

Will I be paid for being in this study?
While there is no monetary compensation for participation, we hope that this study will help you self-manage your IC/BPS symptoms.

What information about me may be collected, used or shared with others?

- Name, address, telephone number/fax number, date of birth
- Social Security number
- Electronic mail addresses
- Medical Record numbers
- Baseline medical information including, duration of IC, previous trials of drugs and therapies, other major medical conditions, and your answers to a set of questionnaires

Why is my information being used?
Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?
The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, including offices that support research operations
- Greenphire employees who administer and process Clincards for compensation
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of the School of Medicine, might receive my information?
Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)

- Penn Institutional Review Board (IRB)

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the study. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?
If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with Dr. Edward Kim. He can be reached at edward.kim@pennmedicine.upenn.edu or 215-439-5257. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the University of Pennsylvania IRB at PROVOST-IRB@pobox.upenn.edu or 215-898-2614.

When you sign this form, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask us. You will receive a copy of this consent document.

_____	_____	_____
Name of Participant (Print)	Signature of Participant	Date
_____	_____	_____
Name of Person Obtaining Consent (Print)	Signature	Date