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

PI: Edward Kim, MD, MPH

Institution: University of Pennsylvania

NCT Number: 05260112

Document date: 02/02/2021

Protocol Details

Basic Info

Confirmation Number:	**didaffdb**
Protocol Number:	**844895**
Created By:	**KIM, EDWARD**
Principal Investigator:	**ARYA, LILY A**
Protocol Title:	**Smartphone-based self-management program for women newly diagnosed with interstitial cystitis/bladder syndrome**
Short Title:	**ERICA**
Protocol Description:	**American Urological Association's 1st and 2nd line therapies such as patient education, bladder retraining, pelvic floor physical therapy, and mind-body therapies are highly effective management strategies for IC/BPS. We developed a smartphone-based program to remotely teach patients with IC/BPS how to self-manage their symptoms, and also provide support and guidance via clinically-validated messages. We plan to test the clinical efficacy of this program for 50 patients.**
Application Type:	**EXEMPT Category 3**

Resubmission*
Yes

Hospital Sites
Will any research activities and/or services be conducted at a Penn Medicine affiliated hospital site?
No

Study Personnel

Principal Investigator

Name:	**ARYA, LILY A**
Dept / School / Div:	**4333 - OB-Obstetrics and Gynecology**
Campus Address Mail Code	**4283**
Address:	**HUP** **3400 SPRUCE ST**
City State Zip:	**PHILADELPHIA PA 19104-4283**
Phone:	**215-662-4144**
Fax:	**-**
Pager:	
Email:	**larya@obgyn.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**
GCP Training Completed:	**Yes**
Training Expiration Date:	**03/11/2023**
Name of course completed :	**Good Clinical Practice: An Introduction to ICH (GCP) Guidelines**

Study Contacts

Name:	**THOMAS, TRACEY**
Dept / School / Div:	**4628 - WM-Ctr for Res on Reprod and Women's Health**
Campus Address Mail Code	
Address:	
City State Zip:	
Phone:	
Fax:	
Pager:	
Email:	**Tracey.Thomas@Pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**
GCP Training Completed:	**Yes**
Training Expiration Date:	**01/13/2023**
Name of course completed :	**Good Clinical Practice: An Introduction to ICH (GCP) Guidelines**

Name:	**VRESILOVIC, JULIA M**
Dept / School / Div:	**4628 - WM-Ctr for Res on Reprod and Women's Health**
Campus Address Mail Code	
Address:	**Suite 810 3701 Market St**
City State Zip:	**Philadelphia PA 19104-0000**
Phone:	
Fax:	
Pager:	
Email:	**Julia.Vresilovic@pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**06/13/2024**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**
GCP Training Completed:	**Yes**
Training Expiration Date:	**07/22/2025**
Name of course completed :	**Good Clinical Practice (GCP) Simulation**

Name:	**KENNEDY, ZANDRA B**
Dept / School / Div:	**4628 - WM-Ctr for Res on Reprod and Women's Health**
Campus Address Mail Code	
Address:	
City State Zip:	
Phone:	
Fax:	
Pager:	
Email:	**Zandra.Kennedy@pennmedicine.upenn.edu**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	
GCP Training Completed:	**Yes**
Training Expiration Date:	**03/04/2025**
Name of course completed :	**Good Clinical Practice: An Introduction to ICH (GCP) Guidelines**

Other Investigator

Name:	**KIM, EDWARD**
Dept / School / Div:	**2100 - Health System**
Campus Address Mail Code	
Address:	**Hospital of the University of Pennsylvania** **Ob-Gyn Residents**
City State Zip:	
Phone:	
Fax:	
Pager:	
Email:	**Edward.Kim@Pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**
GCP Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Responsible Org (Department/School/Division):

4333 - OB-Obstetrics and Gynecology

Key Study Personnel

Name:	**HARVIE, CAMRYN E**
Department/School/Division:	**Research Services**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**
GCP Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**HARVIE, HEIDI S**
Department/School/Division:	**OB-Obstetrics and Gynecology**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed:	**CME Credit for POR Expedited Review - SOM**
GCP Training Completed:	**Yes**
Training Expiration Date:	**07/10/2023**
Name of course completed:	**CITI Good Clinical Practice (GCP) - OCR**

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

HRPP

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)? IF YES, consult the EHRS web site: www.ehrs.upenn.edu/programs/bio/bbpathogens.html for information on OSHA Bloodborne Pathogens requirements (training, vaccination, work practices and Exposure Control Plan). If you have questions, call 215-898-4453.
No

HIPAA / Protected Health Information
Does the research proposal involve accessing (viewing / using), collecting, or disclosing of protected health information (PHI) directly from participants or their medical or dental record for research purposes?
No

HIPAA / Protected Health Information
Does the research proposal involve accessing (viewing / using), collecting, or disclosing of protected health information (PHI) directly from participants or their medical or dental record for research purposes?
No

Remote Study Visits
Does the research proposal involve conducting research visits remotely via any type of video conferencing software?
No

Remote Study Visits
Does the research proposal involve conducting research visits remotely via any type of video conferencing software?
No

CHPS Resources*
Does the research involve CHPS resources?
No

HUP Inpatient Nursing Resources
Does this research include an inpatient admission at HUP?
No

Pathology and Laboratory Medicine Resources*
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
No

Research Involves Apheresis, Cell Collection, and/or Blood Product Collection*
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

Research involving blood transfusion or drug infusions*
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

Trial in Radiation Oncology
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
No

Study in Radiation Oncology
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?
No

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures , whether considered routine care or strictly for research purposes? (UPHS includes all Penn hospitals and clinical practices, including the Clinical Care Associates network of community practices). Examples of UPHS services/tests/procedures includes the Clinical Translational Research Center (CTRC), laboratory tests, use of the pathology lab, cardiovascular imaging tests or radiology imaging tests (whether being billed via the Service Center or through UPHS), other diagnostic tests & procedures and associated professional services, etc.
No

Veteran's Affairs (VA) Patients or Subjects
Does your study involve data from Veteran's Affairs (VA) patients or subjects?
No

If yes, was this approved by the Philadelphia VA?

No

Out of State Research
Will any Penn personnel conduct any research activities outside of the State of Pennsylvania?
Yes

Please identify the location of research activities:

New Jersey

Research involving Virtua Health
Will any Penn personnel conduct any research activities at a Virtua Health site location, OR in collaboration with Virtua Health System personnel, OR using any Virtua Health System resources (e.g., medical records)?
No

Primary Focus*
Sociobehavioral (i.e. observational or interventional)

Protocol Interventions

x	**Sociobehavioral (i.e. cognitive or behavioral therapy)**
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
	Survey instrument
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Business Administrator

Name:	**IMBALZANO, MICHAEL**
Dept / School / Div:	**4322 - NE-Neurology**
Phone:	**215-573-4784**
Fax:	**-**
Pager:	
Email:	**imbalzan@upenn.edu**

Department budget code

000 - 000 - 0 - 000000 - 0000 - 0000 - 0000

Funding Sponsors

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.

Funding sponsors gift
Is this research being funded by a philanthropic gift?

Project Funding*
Is this project funded by or associated with a grant or contract?
No

Sponsor Funding
Is this study funded by an industry sponsor?

Status of contract

The following documents are currently attached to this item:

There are no documents attached for this item.

Protocol

Objectives

Overall objectives
Our objective is to test the clinical efficacy of our smartphone-based self-management education program for IC/BPS (ERICA) on 50 patients with IC/BPS.

Background
Interstitial cystitis/bladder pain syndrome (IC/BPS), a condition of co-existing chronic pelvic pain and urinary symptoms, affects more than 6 million women in the U.S. Though IC/BPS has an immense impact on quality of life, effective treatment options are lacking. In a survey of 1628 females with BPS/IC, Lusty et al reported that female patients with BPS/IC reported that the most effective treatments were opioid analgesics, phenazopyridine, and alkalinizing agents, however, they perceived evidence-based treatments such as amitriptyline and anti-histaminics as only moderately effective. These findings suggest that that there is a disconnect between patient perceived real-world effectiveness of IC/BPS treatments and efficacy reported from clinical trial data and subsequent guidelines developed from this efficacy data. In focus group studies, women with IC/BPS report frustration with the lack of effective treatment options, a sense of isolation, and lack of support from medical care providers as critical elements that worsen their urinary and pain symptoms. Several prior studies have established that patients are willing to communicate with their providers using texting technology. The goal of this proposal is to develop and test a digital platform that would allow women to self-manage their IC/BPS symptoms using evidence-based behavioral treatments.

Study Design

Design
Prospective cohort study

Study duration
To recruit 50 patients, we anticipate 4-6 weeks to recruit and enroll patients on a rolling basis until we have all 50. Each subject will participate in the study for 6 weeks. We will begin recruiting as soon as we have IRB approval for this modification. For 50 patients to complete the program, we anticipate approximately 3-4 months. We plan to allot 1-2 months afterwards for data analysis and manuscript preparation.

Characteristics of the Study Population

Target population
Women newly diagnosed with interstitial cystitis/bladder pain syndrome. Inclusion criteria: women who have access to a smart phone with text messaging capability and are able to read and write English. Exclusion criteria: women with recurrent urinary tract infections, neurological conditions such as multiple sclerosis, recent (within 6 months) of surgery or pregnancy, prior radiation to pelvic area.

Subjects enrolled by Penn Researchers
50

Subjects enrolled by Collaborating Researchers
0

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Participant recruitment
Please describe the plan to equitably identify and recruit a diverse group of participants that is reflective of the population under study. If this is a multicenter protocol, the recruitment plan should describe the local (Penn) site's plan. Describe:how potential participants may be identified (review of medical records, Slicer Dicer, DAC reports including referrals from physician offices and clinics);who may approach potential participants;methods to achieve sample diversity and inclusiveness;what information may be presented to or discussed with them; andthe context and setting in which recruitment will happen.
Modification: Dr. Kristene Whitmore, a urologist who specializes in IC/BPS and practices at Virtua Health, will disseminate information about the study to her patients who may be eligible. She will only inform them that there is a remotely-delivered self management education study conducted via Penn that they may be interested in and our study coordinator's contact information. She will not be responsible for recruitment, consent, or enrollment. Please note that no Virtua Health resources, including their electronic medical records, will be used. Prospective recruitment: Female patients with interstitial cystitis/bladder pain syndrome (IC/BPS) will be recruited from the clinical practices of Penn Urogynecology and Penn Urology. Urogynecology and urology providers outside of Penn can direct interested and eligible patients to the study. The study team will reach out to these patients to overview the program. Patients who are interested in participating will follow the same consent and enrollment process. We will also have a visual ad and accompanying text to be posted on social media accounts (Facebook, Instagram, Twitter) of IC Association (non-profit organization supporting patients with IC/BPS) [IRB and Penn social media committee APPROVED previously]., and via video presentation

during ICA's self-care-oriented online event [Script APPROVED by the IRB]. Interested patients will have a phone call with one of the clinicians on the study team to confirm eligibility and undergo the same consent and enrollment process as those recruited from our clinical practices. Retrospective recruitment: Female patients with IC/BPS who were seen by a faculty practices of Urogynecology and Urology will be identified by retrospective chart review. These patients will be messaged using my PennMedicine patient portal to reply to the message if they are interested a potential research study (recruitment script attached). Overall, recruitment will end when 50 subjects have been recruited. At a time mutually agreed upon by the interested patient and a research team member, study information will be presented to them over the phone. Risks and benefits of participation in the study will be discussed. Consent form will be signed via Penn's RedCAP platform. https://redcap.med.upenn.edu/surveys/?s=DE4R83PAJ3 Confidentiality will be maintained throughout the recruitment process as well as during study participation.

Recruitment Materials
Is the research team using any recruitment materials? These may include but are not limited to: phone call scripts, radio/video scripts, flyers/brochures, internet postings, email, letters to potential participants, letters to patient physicians, My Penn Medicine (MPM), other direct messaging, etc. For guidance regarding recruitment materials, please review the IRB's guidance on Participant Recruitment Materials online:https://irb.upenn.edu/mission-institutional-review-board-irb/guidance
No

Use of Penn Media & Social Media Services
Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
Yes

Please identify which method(s) of social media you will utilize, the content of the text to be used, and the method(s) for posting this information (i.e., using Penn supported communication services). When proposing the text to utilize, please be aware of any social media limitations (i.e., number of characters allowed in a tweet) and any appropriate confidentiality practices necessary to be compliant with posting research recruitment text.NOTE: Penn Medicine must utilize one of the centralized PM Facebook Pages:ClinicalResearch@Penn Facebook pagePenn Medicine Facebook page@PennCancer Facebook pageAll clinical research paid Facebook ads must be listed on Clinical Research @ Penn Facebook page,www.facebook.com/ClinicalTrialsAtPenn. Exceptions to the above must get approval from the Penn Medicine Social Media Committee: pennmedicinesocialmediacommittee@uphs.upenn.edu.
[Previously IRB and Penn social media committee APPROVED]. We plan to have IC Association (non-profit organization supporting patients with IC) post the information about our study on their social media accounts (Facebook, Instagram, Twitter). The visual ad is attached (please note that Facebook and Instagram ads should contain less than 20% texts thus, we will relay the information required by the IRB and OCR in the text accompanying the visual ad. "If you have interstitial cystitis, Drs. Lily Arya and Edward Kim at the University of Pennsylvania's Division of Urogynecology are conducting a research study to teach patients how to self-manage their symptoms. In this completely remote, smartphone-based study, you will receive video treatment modules and check-in messages via a secure texting platform over 6 weeks (max 3 texts per week). If you are women over 18, recently diagnosed with IC, have a smartphone and interested in evidence-based, holistic ways to manage your symptoms, please call our study coordinator Lisa at 267-600-2484." Once they contact us through our study coordinator, we will set them up for a phone call with one of the clinicians on our team to confirm eligibility. They will then undergo remote consent and enrollment process with our study coordinator.

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)? Centeral nervous system(CNS) effect: the ability of a test article to enter into and potentially interact with the central nervoous system (brain and spinal cord). Clinical Investigation: Any experiment that involves a test article and one or more human subjects that either is subject to requirements for prior submission to the Food and Drug Adminstration (FDA) under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to the requirements for prior submission to the FDA under these sections of the act, but, the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
No

Procedures
Eligible participants will be consented via phone or video conferencing (patient choice) with our study coordinator. Then they will be asked to choose a treatment pathway that they are interested in (pelvic floor physical therapy, regulating brain-bladder connection, mindfulness practice). Then they will complete the following validated, published questionnaires: - Interstitial cystitis problem index - Interstitial cystitis symptom index - Pain self efficacy score - Hospital anxiety and depression score - Patient physician communication satisfaction Then the patient will participate in a 6-week texting program. They will receive the following evidence-based, standard-of-care treatments for IC/BPS delivered via text messages: patient education about IC/BPS, urinary urge suppression exercise instructions, pelvic floor physical therapy instructions, mindfulness practices, cognitive behavioral therapy focusing on regulation the brain-bladder. connection, and instruction on how to avoid common dietary triggers. Video modules will be texted out twice a week (Monday and Wednesday). Every Friday, they will receive a check-in message. If they report severe symptoms, they will be asked if they would like to be contacted via phone by a clinician to triage symptoms. After the completion of the program, the participants will complete the same set of questionnaires that they did at baseline. In addition, they will complete the Net Promoter Score and Systems Usablility Scale, which are validated questionnaires to evaluate the quality of a technological program. Confidentiality will be maintained throughout the recruitment process as well as during study participation.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception? Deception could be considered any direct misinformation presented to the subject or omission of key information pertaining to the design or nature of the project.
No

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
Response rate to text messages will be determined. We will also compare score of the validated questionnaires before and after participation in the texting project using paired t-test. P values 0.05 will be considered significant.

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject Confidentiality
Each person will be assigned a study ID number. The file linking study participants to study ID will be stored in a password protected file to which only study personnel will have access. For text messages, We will utilize Way to Health platform which assures data security and privacy (https://www.waytohealth.org/files/W2H.Summary.of.Data.Protections_2020-06-03.docx). Text messages will be stored in a secure inbox of the Penn Center for Health Care Innovation. As with any Way to Health text messages, Texts will not contain any identifying information other than the participants' names to personalize each message (e.g. "Good morning, X!"). Participants will also be instructed to not text personal information per Way to Health standard procedures. All patients will be provided a telephone number they can call to talk with study clinician about questions. All demographic and questionnaire data will stored in secure files using patient ID and to which only study personnel have access.

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record? [NOTE: This does not apply to: 1) research information that would not normally be included in the electronic medical record or 2) information that is in the electronic medical record as part of clinical care.]
No

Disclosures
Will any data or specimens from Penn participants OR other research generated work product (e.g., intellectual property) be disclosed to any individuals, entities, or vendors, etc. outside of Penn?
No

*Data Protection**

- x **Name**
- x **Street address, city, county, precinct, zip code, and equivalent geocodes**
- x **All elements of dates (except year) for dates directly related to an individual and all ages over 89**
- x **Telephone and fax number**
- x **Electronic mail addresses**
- x **Social security numbers**
- x **Medical record numbers**
- **Health plan ID numbers**
- **Account numbers**
- **Certificate/license numbers**
- **Vehicle identifiers and serial numbers, including license plate numbers**
- **Device identifiers/serial numbers**
- **Web addresses (URLs)**
- **Internet IP addresses**
- **Biometric identifiers, incl. finger and voice prints**
- **Full face photographic images and any comparable images**
- **Any other unique identifying number, characteristic, or code**
- **None**

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Consent

1. Consent Process

Overview
At a mutually agreed upon time, over the phone or video conferencing (patient choice), an interested patient and a study team member will review the texting program, the consent form, risks, benefits, and alternatives. It will be emphasized that this program is an adjunct to the treatment plan and stress that their participation will have no bearing on their existing treatment plan. Patients may opt out at any time during the study period if they find it to be too burdensome. All questions will be addressed. The patient will then be directed to the consent form that they can sign via RedCAP.

Risk / Benefit

Potential Study Risks
Risk of participation is minimal. This study is testing a smartphone-based program to remotely deliver evidence-based information on IC/BPS self-management. No new treatments are being tested. All treatments delivered through this platform are within standard of care. There is a potential risk of loss of confidentiality if subjects share their personal information (via free-texting) other than what is asked by the study team.

Potential Study Benefits
Patients may derive some benefit from being reminded of their prescribed treatment strategies.

Risk / Benefit Assessment
Minimal risk

General Attachments

The following documents are currently attached to this item:

Cover Letter (2023.03.17_irbmod_addpersonel_coverletter.docx)