Empowering Women and Providers for Improved Care of Urinary Incontinence (UI) [EMPOWER Study]

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UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES

Project Title: Empowering Women and Providers for Improved Care of Urinary Incontinence (UI) [EMPOWER Study]

Principal Investigator: Adonis Hijaz, MD

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why are you being invited to take part in a research study?

You are being asked to participate in this research study because you have one or more symptoms related to urinary incontinence (problems controlling your urine).

Things you should know about a research study

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Introduction/Purpose

Urinary incontinence (UI) affects over 50% of women in the United States and is often unrecognized and untreated. The purpose of this research study is to evaluate how to improve care for women with urinary incontinence. This study is being conducted throughout the Primary Care Institute practices of the University Hospitals Health System (UHHS) and will include primary care providers and any interested women from up to 109 primary care practices.

This research is funded by a grant from the Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov. Visit www.ahrq.gov/evidencenow/projects/urinary for more information.

Key Study Procedures

If you decide to participate in the study, it involves completing questionnaires and allowing us collect information from your visits with your primary care provider. As part of your usual medical care, you may receive recommendations to help with your urinary incontinence like awareness, education, behavioral therapy, physical therapy, medications or other treatments. Any recommendations would be standard suggestions for care and not experimental treatments for this study. The study may also involve using a web application (called a chatbot) for education and reminders and/or talking with a Nurse Navigator. More detailed information about the study procedures can be found under "Detailed Study Procedures."

Key Risks

The main risk with this study is emotional discomfort due to answering questionnaires. There are no physical risks associated with the other study activities. The risks of any recommended treatment would be explained by your primary care provider or a specialist provider as part of your usual care.

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More detailed information about the risks of this study can be found under "Detailed Risks."

Benefits
There may or may not be a direct benefit from your participation in this study. This study is providing additional training for some providers and educational material to all participants. If you are in the part of the study that uses the chatbot and/or interacts with a Nurse Navigator, you may find that activity helpful in managing your symptoms. Your participation may provide benefit to future patients by helping the researchers determine ways to improve healthcare for women with urinary incontinence.

Alternatives to Study Participation
Participation in this study is completely voluntary and does not offer any new treatments for your urinary incontinence. You can decide to participate or not to participate. If you choose not to participate in this study, you and your provider can continue as usual to treat your condition.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Detailed Study Procedures
This study is divided into three groups. Each UH Primary Care practice participating in this study is assigned to a study group. If you decide to participate in this research, your study activities will be determined by which group your primary care practice is in.

If you join this study, you will be in Group _____.

The study activities are described in detail below.

For ALL participants in ALL Groups:

- You will be asked to complete brief **questionnaires** about your symptoms, quality of life, discussions about incontinence, interactions with your healthcare provider, and treatments considered. The questionnaires are completed online through a link we will send to your email. In total, the questionnaires will take about 20 minutes or less **at the following times: Enrollment, Week 8, Month 6, and Month 12.**
- As part of the first set of questionnaires, we will collect some general information about your medical history and your demographics as explained below:

  - **Demographics** which includes things like gender, race, ethnicity, age, income, education
  - **Limited medical history** which includes things like smoking history and other diagnoses or medications that may affect UI

- You will be provided with **educational material** about managing UI.
- As part of your **clinical care**, you are encouraged to discuss your symptoms with your primary care provider or another specialist and your provider may make recommendations for urinary incontinence management. Your usual clinical care is not determined by this study.
- The study team will **collect information (data) from your medical record** related to your care (for example, medical history, follow-up appointments, treatment recommendations, test results, physical therapy, medications, referrals, etc.) during the time you are in this study. Your incontinence screening survey will be part of the medical record review for this study.
- You will receive occasional updates about the study's overall outcomes and progress by email. After receiving the first update, you may opt out of these updates at any time if you wish by replying "opt out."

Group 1 participants:

- There are no other research activities beyond what is described above for "ALL groups."
- Your total time commitment for the study activities will be approximately 2 hours over 12 months.

Group 2 participants:

- In addition to what is described above for "ALL groups," **you will be connected with a Nurse Navigator** who will help guide you in your UI management efforts. The Nurse Navigator can provide additional education about UI and support for the recommendations made by your provider. Over the course of 8 weeks, you and the Nurse Navigator will have 4 phone calls or Zoom calls that are about 10-20 minutes each **at the following times: Enrollment, Week 2, Week 4, and Week 8.**
- Before we schedule your first Nurse Navigator call, we will ask you some questions about your symptoms and if you have tried anything to address urinary incontinence issues. This will take 10 minutes or less.
- Your total time commitment for the study activities will be approximately 3 hours over 12 months.

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Group 3 participants:

- In addition to what is described above for "ALL groups," **you will be connected with a Nurse Navigator** who will help guide you in your UI management efforts. The Nurse Navigator can provide additional education about UI and support for the recommendations made by your provider. Over the course of 8 weeks, you and the Nurse Navigator will have 4 phone calls or Zoom calls that are about 10-20 minutes each **at the following times: Enrollment, Week 2, Week 4, and Week 8.**
- Before we schedule your first Nurse Navigator call, we will ask you some questions about your symptoms and if you have tried anything to address urinary incontinence issues. This will take 10 minutes or less.
- You will **use a chatbot called CeCe** that has been created to help you in your management of urinary incontinence. This chatbot is a program you can access by a website using a smartphone, tablet or computer. CeCe is experimental, which means that the U.S. Food and Drug Administration (FDA) has not approved it for use as a tool for all patients. The goal of the CeCe chatbot is to interact with you to provide education and to help you to manage UI. CeCe will also ask you questions that you can answer on the screen. You will use CeCe for about **5-10 minutes a day for 8 weeks**.
- Your total time commitment for the study activities will be approximately 8 hours over 12 months.
- For some of the participants in this group, de-identified data from your interactions with the chatbot will be shared with the FDA in an application for the approval of this chatbot technology.
- University Hospitals Cleveland Medical Center has financial interests relative to Renalis, the company that created the CeCe chatbot, but will not benefit financially from the outcomes of this research.

Below is a summary of the study activities for each groups:

Group 1	Group 2	Group 3
Usual care	Usual care + 4 calls with Nurse Navigator	Usual care + 4 calls with Nurse Navigator + 8 weeks using CeCe (chatbot)

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ALL Groups
Questionnaires at 4 points in time: Enrollment, Week 8, Month 6, and Month 12 Data collection from you and your medical record

Optional Interview: A small number of participants from each group will be invited to do one optional interview about the experience of participating in this study. It is not required, so you can say yes or no to the interview and still be in the rest of the study.

The interview will take about 30 minutes and be done by phoning in to a Zoom session, by joining a Zoom session online, or in person. If you do the interview by an online Zoom session, you can choose whether you want to be on video or not and if your name is displayed or not. However the interview is completed, it will be recorded to the UH Zoom Cloud. If you choose to be on video during the online Zoom session, the recording feature automatically records both audio and video; however, we will immediately delete the video recording file. The audio recording file will be transferred to a secure computer drive with access limited to study team members only. The audio recording will then transcribed (typed) into a written document that will be used for the study. We ask that you do not provide any identifying information during the interview, but if you do mention anything that is identifiable, we will NOT include it in the transcription.

Detailed Risks

Questionnaires and optional interview: Some of the questions may cause you to feel uncomfortable. If you do not wish to answer a question, you may skip it.

Breach of confidentiality: There is a risk that someone without our permission might view your data either by accident or by hacking the data. We are protecting against this by keeping all of the data separate from your name and in password protected documents/databases on secure computers/systems.

Risks that are not known: You will be informed if new risks are identified.

Consequences of Withdrawing from the Research

If you decide to stop participating in the study for any reason, it is important to let the study team know as soon as possible. Withdrawing from this study will not change your regular medical care in any way and you would continue routine clinical care as discussed between you and your provider. The data collected from you and from your medical record to the point of withdrawal will remain part of the study database and may not be removed. The study team may ask if they can continue to collect standard of care data from your medical record, but this is your choice.

If you are in Study Group 2 or 3 and stop participating in the study, you will no longer have access to the study's Nurse Navigator or the CeCe chatbot.

Financial Information

The main study does not provide any compensation. There is no cost to you for the following research activities: questionnaires, Nurse Navigator support, or using CeCe. If you are in the group using CeCe, standard messaging and data rates may apply.

This study is not paying for any of your medical bills. You are responsible for all of the costs of your clinical care including visits with your primary care provider, any laboratory testing or medications prescribed for your medical care, any other referrals or treatment recommendations. If you have any questions about your level of insurance coverage for your clinical care, you are advised to contact your insurance provider.

If you complete the optional interview for the study, you will receive a $30.00 payment for your time spent taking part in the interview. Payment will be made in the form of a check, mailed to your residence. To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS. You will be issued a 1099-Misc form only if payment exceeds $600 from all studies in which you are participating, in a fiscal year.

Clinical Trial Information

U.S. NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL TRIAL DATABASE: 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 to find out information about the trial and basic results. The ClinicalTrials.gov Identifier to look up this study is NCT05515198.

Confidentiality

To maintain confidentiality, your data will be coded with a unique study ID number and not stored by your name or other information that could directly identify you. Only members of the study team will have access to the link between your study ID number and your name. Your study documents and data will be stored in secure locations with access limited to the study team.

Efforts will be made to keep the personal information in your research record confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If your records are reviewed your identity could become known.

If identifiers are removed from your identifiable private information that is collected during this research, this information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

University Hospitals/Case Western Reserve University Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor (unless your supervisor is also a member of the study team).

Privacy of Protected Health Information (HIPAA)

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "Empowering Women and Providers for Improved Care of Urinary Incontinence (UI) [EMPOWER Study]" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Adonis Hijaz, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally, the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: full name, address, date of birth, dates of encounters/test results, telephone number, email address, and medical record number. This PHI will be used to contact you during the study if needed, to extract information from your medical chart, and help the study evaluate ways to improve care for women with urinary incontinence. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: UH Primary Care Institute providers and management, UH Physical Therapy (if applicable), our collaborators at Case Western Reserve University, Renalis (the

company that provides access to and manages the CeCe chatbot), other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; any UH or CWRU employee required to process information for research, finance, compliance, or hospital operation, and Government representatives or Federal agencies, when required by law. It is possible, that in the future, additional research sites may be added. In this event, your PHI that was collected during this research project may be shared with research personnel at these additional sites.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Adonis Hijaz, University Hospitals Cleveland Medical Center, Urology Institute, 11000 Euclid Avenue, Lakeside 4554, Cleveland, OH 44106; If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of Your Rights as a Participant in a Research Study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. De-identified data from this study may be published, presented, or otherwise made publically available. If this happens, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center

(UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of Your Study Records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact Information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator, Dr. Adonis Hijaz, can also be contacted at 216-844-3009. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Optional Items

Text Messaging: Please check "yes" or "no" below to indicate if you are willing to receive text messages/reminders during the course of the study.

Yes _____ No _____ Initials _____

If yes, add phone number for texts: _____
You may opt-out of text messaging at any time during the study.

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Optional Interview: Please check "yes" or "no" below to indicate if you are willing to participate in the optional 30-minute interview if you are invited.

Yes _____ No _____ Initials _____

Future use of Identifiable Data: It is possible that some of the identifiable data collected during this research project may be helpful for other project(s) as well. If this is the case, we would like to ask your permission to use your identifiable data in these project(s). The identifiable data that may be retained include your zip code and dates related to you and your medical care and study visits. Please check the option that correctly indicates your choice.
My identifiable data may be used for future research:

Yes _____ No _____ Initials _____

Consent to Contact for Future Research: Our study team may have additional research studies in the future. We would like your permission to contact you in the future if we think you could be a potential participant in one of our studies. Please check "yes" or "no" below to indicate your choice about contact for future research.

May we contact you about future research opportunities?

Yes _____ No _____ Initials _____

If yes, fill in which way(s) we can contact you (phone, email, or both):

Phone _____ Email _____

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

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X		
Signature of participant	Date	Time
X		
Printed name of participant		

X		
Signature of person obtaining informed consent	Date	Time
X		
Printed name of person obtaining informed consent		