University of Pittsburgh
Department of OB/GYN
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Pittsburgh, PA 15213

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: A Randomized Pilot and Feasibility Study of a cultuRE-Directed approach to Urinary traCT Infection symptoms in Older womeN: a mixed methods evaluation – the REDUCTION trial

PRINCIPAL INVESTIGATOR:

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KEY INFORMATION SUMMARY

You are being asked to participate in a research study, which is completely voluntary. The study's team members will explain the details of the study and answer any questions you have regarding the study. This study focuses on two different ways to manage urinary tract infection symptoms in older women. Duration of involvement in this study is for 4 weeks and there will be 70 enrolled. If you participate in the study you will be assigned randomly to either watch your symptoms until urine testing comes back or start an antibiotic early. The study team is testing your symptoms at the time they start, when your urine testing comes back and then weekly for 4 weeks after symptoms. Please be reassured that you will receive antibiotics if they are necessary regardless of your assignment in the study. The first research encounter can either be done remotely or in-person based on your preference. You will be asked to complete some questionnaires at each of these time-points. We will make every attempt to protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University. There is no direct benefit to you for participant in the study. However, this study will help providers to better understand the pros and cons of early antibiotics for urinary tract infection symptoms. If you decide not to participate in this study, you will continue to receive clinical care from your provider as you have planned together.

Why is this study being done?

This is a research study to evaluate the pros and cons of early antibiotics for urinary tract infection symptoms in older women. Currently, it is unknown who really needs antibiotics for management of urinary tract infection symptoms.

Studies in women who do not receive antibiotics for urinary tract infection symptoms show that up to 50% will improve without antibiotics and that it is a generally safe approach. This study will help to improve our understanding of how women do with either early antibiotics or only antibiotics if needed after urine testing for urinary tract infection symptoms.

Who is being asked to take part in this study?

Approximately 70 women from both the University of Pittsburgh Medical Center (UPMC) and through the Pitt+Me research registry who are at least 65 years old and have a history of recurrent urinary tract infections will be enrolled in this study.

Women are being asked to enroll even if they do not currently have symptoms of a UTI and that when symptoms begin, the participant should contact the study team

What is the duration of participation in this study?

If you agree to participate and are eligible, your participation will be requested for 4 weeks after urinary tract infection symptoms start.

What are the procedures of this study?

1. If you agree to participate in this research study, you will complete a baseline assessment, which will be within 24 hours of when you call with urinary tract infection symptoms. This visit can be done either remotely or in person. This is encounter #1.
2. Before in-person appointments: Investigators will take appropriate measures to ensure that research subjects are not displaying symptoms or have been in known contact with COVID-19 before their participation in research. We will ask participants to wear a mask to the appointment if they have one.
3. Before remote sessions*:* Prior to videoconferencing assessments, study staff will help participants set up for sessions using their own device such as a laptop, iPad, etc.,
4. During **eencounter #1**, you will complete questionnaires and be asked to provider a urine sample (either on site for in-person visit or to a local lab if you have your visit completed remotely).

Questionnaires: You will be asked to complete some questionnaires that you will fill out on your own. These will take approximately 20-25 minutes to complete. Questions will be answered either on paper or a computer.

Urinary Tract Infection Symptom Assessment: A set of measures that ask about current urinary tract infection symptoms. This will take approximately 5 minutes.

Pelvic Floor Distress Inventory Scale: A set of measures that ask about urinary, fecal and other pelvic floor symptoms. This screen takes approximately 5 minutes to complete.

Interview/Chart Review: Study staff will record research data from your medical record. All of this information was collected as part of previous clinical visits with your doctor. Study staff will simply record some of this information on study forms (that do not contain your name or other identifying information). Things that they will record include your age, race, ethnicity, body mass index, current medications, smoking status, education level, medical and surgical history, and information about your gynecology history. During your study visit, a member of the research staff will conduct an interview to verify this information. This will take approximately 10 minutes.

At the end of encounter #1, you will be updated on when to expect questionnaires to be sent and have study staff call you which will take place at week 1, 2, and 3 after your baseline visit.

5. You will then be randomized (like the flip of a coin) to either receive antibiotics that day or wait until your urine culture results return. All participants will be allowed to use acetaminophen, non-steroidals, and/or phenazopyridine (also known as Azo which is an over the counter agent for UTIs). If you are in the early antibiotic group, we will choose an antibiotic with consideration of patient reported allergies, current medications and current guidelines. All antibiotics are FDA approved for treatment of urinary tract infection. If there is a contraindication to the first antibiotic on the list below we will progress to the next option until a suitable selection is achieved.

- Nitrofurantoin orally twice a day for 5 days
- Trimethoprim/Sulfamethoxazole orally twice a day for 3 days
- Fosfomycin orally once
- Cephalexin orally twice a day for 5 days
- Ciprofloxacin orally twice a day

6. Once your urine culture results return (which usually takes 2-3 days) we will either start an antibiotic if you were in the "wait for testing" group and your urine culture is positive or we will stop the antibiotics in those already on them for a negative urine culture.

Encounters #2/#3/#4: Questionnaires and Side Effects

The Urinary Tract Infection Symptom Questionnaire and a series of questions about potential medication side effects will be sent to you via email. A study team member will also call you to make sure that you were able to complete these questionnaires on the computer. If you have issues with the electronic format you can complete the questions over the phone.

All participants will complete the questionnaires, including those who start antibiotics, those who stop antibiotics, and those who were randomized to the "wait for testing" group and received a negative urine culture result.

What are the possible risks and discomforts of this study?

Recording information from your medical record: There is the small chance of loss of confidentiality of your medical information. We take great care to minimize this chance by not recording your personal information (like your name) on forms and keeping our records in a locked office and in a password protected data server.

Questionnaires: You may feel embarrassed answering some of the questions or the questionnaires may cause distress. Although we encourage you to answer all of them, you may skip those which make you feel uncomfortable.

Antibiotic side effects: You may experience side effects from your antibiotics prescribed either at the beginning of symptoms or after your urine testing returns. Antibiotic side effects may consist of an allergic reaction, upset stomach, diarrhea, or rash.

Worsening of urinary tract symptoms: This could occur in those who receive early antibiotics or also in those who are waiting for urinary results. For those who wait for urinary results before starting antibiotics, an infrequent risk is that the infection may increase in severity, which may result in hospitalization or inflammation of the kidneys. Importantly, this is a risk to anyone who is experiencing a urinary tract infection. The study team will be available for you to call and discuss at any time. You will also be allowed to take non-prescription medications for your symptoms as you desire (like ibuprofen).

As with any experimental procedure, there may be adverse events or side effects that are currently unknown and some of these unknown risks could be permanent, severe or life-threatening

You may call 412-641-7850 or 412-641-6881 24/7 to talk to a member of our research team.

Will I benefit from taking part in this study?
You may not experience any direct benefit from being a participant in this study. However, the information we gain from this study will give us an understanding of the preferred option to manage women with urinary tract infection symptoms.

You will be provided with the results from your urine culture and the management of this will be based on the results, your symptoms the clinical judgement of the clinical team.

Will anyone know that I am taking part in this study?
All records pertaining to your involvement in this study are kept strictly confidential (private) and any data that includes your identity will be stored in locked files. Your identity will not be revealed in any description or publications of this research. If medical records are shared they will be de-identified. Safeguards will be used to minimize breach of confidentiality. This will include labeling all data with a study number rather than your name or other direct identified.

What treatments or procedures are available if I decide not to take part in this research study?
You do not have to participate in this study. You will continue to receive all typical care provided to women with urinary tract infections.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?
You and/or your insurance will be charged, in the standard manner, for any urinary tests that are ordered or antibiotics that are prescribed along with medical visits for your routine medical care. This includes any visits to your doctor for your medical care. You will be responsible for any co-pays, coinsurances, or deductibles associated with your clinical visits. The proposed antibiotics have different costs associated with each, but that the cost of the antibiotic will not be considered when prescribing the antibiotic.

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of the research study. These procedures include medical record abstraction and study questionnaires.

Will I be paid if I take part in this research study?
You will be paid $50 (Vincent card) at the completion of the 4-weeks and additionally, we will provide one free parking voucher if you chose to have your first visit at Magee Women's Hospital.
All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 26% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 74% of the expected payment.

Your data used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

Who will pay if I am injured as a result of taking part in this study?

University of Pittsburgh researchers and their associates who provide services at the University of Pittsburgh Medical Center (UPMC) recognize the importance of your voluntary participation in their research studies. These individuals and their staff will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that the research procedures have resulted in an injury to you, immediately contact Dr. Bradley at the number listed on the first page. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other health care provider (for example, your physician's office records). This information that will be recorded will be limited to information concerning your urinary tract infection history and/or current symptoms (for example, diagnostic information, lab and scanned results, medications, medical history). This information will be used to determine your eligibility for this study and to follow your response once you are enrolled in the study. Research data will not be placed in your medical record, but your urine culture from the study (which is ordered as part of your clinical care) will be available. The medical record will be available to the research team of investigators indefinitely.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of internal hospital operations (i.e. quality assurance).

Authorized representatives of the University of Pittsburgh's Office of Research Protections may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Your data may be used for future research or shared with other investigators; however, the information will be used or shared in a de-identified manner.

Your information collected as a part of this research, after removal of identifiers, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of seven years after final reporting or publication of a project.

Is my participation in this research study voluntary?

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your doctor may be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If you withdraw from the study and you would still prefer to be seen by our clinical team for your urinary tract infection symptoms then we will provide you with the information to set up an appointment as per clinical care.

What other information is relevant to participation in this study?

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Voluntary Consent

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may always contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study and authorize Dr. Bradley and her team to access my medical records for the purposes described in this form. A copy of this consent form will be given to me.

_____ _____

Participant's signature Printed name of Participant

_____

Date

Certification of Informed Consent

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
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_____	_____
Signature of Person Obtaining Consent	Date