Improving Primary Care Understanding of Resources and Screening for Urinary Incontinence to Enhance Treatment (PURSUIT)

Funding Agency: Agency for Healthcare Research and Quality (AHRQ)

Birmingham VA Site Principal Investigator/Study Chair: Lisa Zubkoff, PhD

Overall Principal Investigator: Alayne Markland, DO, MSc

March 7, 2024

NCT05438849

Department of Veterans Affairs

RESEARCH CONSENT FORM

Version Date: (07/19/23)

Participant Name: _____ Date: _____

Title of Study: Improving Primary Care Understanding of Resources and Screening for Urinary Incontinence to Enhance Treatment (PURSUIT)

Principal Investigator: Alayne Markland, DO, MSc VA Facility: Birmingham and Atlanta

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a program that is being funded by the Agency for Healthcare Research and Quality (AHRQ). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This program will assess the helpfulness of delivery of treatment methods for bladder leakage or urinary incontinence (UI) for Women Veterans. By doing this study, we hope to learn more about the helpfulness of this delivery method for treating Women Veterans with bladder symptoms.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

For this phase of the PURSUIT Program, we are conducting one-time telephone interviews with program participants. The interview may last 30-45 minutes. During the telephone interview, the interviewer will ask questions to get your feedback on your experience with the PURSUIT Program and the MyHealtheBladder application.

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

The feedback that you provide during the phone interview will help us learn more about how to improve remote treatment methods fror Women Veterans who may be experiencing bladder leakage and/or urgency. For a complete description of benefits, refer to the Detailed Consent.

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

The most important reason to not take part in this phase of the program is if you are unwilling to participate in a telephone interview regarding your experience with the program. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

Participant Name: _____ Date:_____

Title of Study: Improving Primary Care Understanding of Resources and Screening for Urinary Incontinence to Enhance Treatment (PURSUIT)

Principal Investigator: Alayne Markland, DO, MSc VA Facility: Birmingham and Atlanta

The person in charge of the study is Alayne Markland, DO, MSc of the Birmingham Veterans Affaris Medical Center (BVAMC). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: (205) 558-7064.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn more about the usefulness of a remote delivery treatment methods for treating bladder leakage in women Veterans. This treatment delivery method involves standard of care treatment that is currently used in the VA Continence Clinic. In this phase of the program, we hope to get feedback from program participants regarding your experience with the PURSUIT Program and the MyHealtheBladder application.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 3 years. Your individual participation in this phase of the project will take up to 30-45 minutes. There will be up to 100 total participants enrolled to complete a telephone interview at the program's participating sites (all within VISN7).

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you agree to participate in this study, you will be asked to participate in a one-on-one, one-time telephone interview with one of our program interviewers. The interviewer will ask you open-ended questions about your experience with the PURSUIT program and the MyHealtheBladder application.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

There is minimal risk involved with this phase of the PURSUIT Program. You may experience some discomfort being asked questions about your opinion and experience with the intervention. As a participant, you can skip any questions that you prefer not to answer.

- **Photographs, audiotaping, or videotaping**
  The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by the study investigators while you are participating in this study. You also authorize disclosure of the voice recording to Same Day Transcriptions Services, 11523 Palmbrush Trail, Suite 102 Lakewood Ranch, FL 34202. The said voice recording is intended for the following purposes: Audio-recording will be used for participant interviews. After the interview is completed, the Same Day Transcription Services will write out your interview word-for-word. When the text is complete, our team will analyze the interviews from participants to look for common thoughts or statements.

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Expiration Date:

The study team has also explained that you will not receive any royalty, fee, or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded and may withdraw your consent for up to a reasonable time before the voice recording is used.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You will not get any direct benefits from taking part in this research study. However, your feedback will help us learn more about improving bladder leakage treatment methods for women Veterans.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

For purposes of this research, study data will be stripped of all individual identifiers and each participant will be given a unique code for the study. Paper and electronic patient records will be stored in a secure folder or locked cabinet in a locked office. These records will only be accessible to the Principal Investigator, Program Interviewer, and Program Coordinator.

Identifiers might be removed from the identifiable private information that is collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

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.

WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

There will be no cost to you to participate in the telephone interview for this VA research project.

Compensation/Payments
You will be compensated $20 for participating in the telephone interview.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

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There are no known health risks associated with this phase of the study.

If you should have a medical concern because of taking part in this study, call:

> DURING THE DAY: Dr. Alayne Markland at (205) 558-7064, or
> AFTER HOURS: UAB paging at (205) 934-3411 ask to page Dr. Alayne Markland. If you are unable to reach the health care provider listed and need immediate medical assistance for a research-related injury, please call the VAMC Emergency Room at (205) 558-4725 to obtain advice.

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary and you may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and discontinue participation at any time. If you decide to withdraw from this study, you are asked to contact Dr. Alayne Markland at (205) 558-7064 during the day. Evenings or weekends, call UAB paging (205) 934-3411 and ask them to page Dr. Alayne Markland.

If you are a VA employee, refusal to take part in the study will in no way influence your employment, ratings, or subsequent recommendations. You may discontinue taking part in the study at any time without penalty or loss of benefits. You may withdraw and receive standard of care that you would otherwise have received.

If you chose to withdraw from the study, the study doctor will continue to review the data collected prior to withdraw. However, the study cannot collect further information.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions regarding the study, please call Dr. Alayne Markland at (205) 558-7064 during the day. Evenings or weekends, call UAB paging at (205) 934-3411 and ask them to page Dr. Alayne Markland or the Geriatric physician on call.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Institutional Review Board (IRB) at (205) 933-8101, ext. 335393. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the program coordinator at (205) 933-8101, ext. 337319, if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

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Any significant new findings that develop during the research study that, in the opinion of the investigator, may affect your willingness to continue to participate will be provided to you as soon as possible.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The Investigator, Certified Registered Nurse Practitioner, or Program Coordinator has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it. A copy of this signed consent will also be put in my medical record.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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Participant Name: _____ Date: _____

Title of Study: Improving Primary Care Understanding of Resources and Screening for Urinary Incontinence to Enhance Treatment (PURSUIT)

Principal Investigator: Alayne Markland, DO, MSc VA Facility: Birmingham and Atlanta

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You are being invited to take part in a research study that is being funded by the Agency for Healthcare Research and Quality (AHRQ). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is about assessing the helpfulness of the PURSUIT Program in providing treatment for bladder leakage or urinary incontinence (UI), in women Veterans. It is being funded by the Agency for Healthcare Research and Quality (AHRQ). By doing this study, we hope to learn how helpful the PURSUIT Program is to improve understanding of screening for and treatment of urinary incontinence in women Veterans.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

For this phase of the PURSUIT Program, we are conducting one-time telephone interviews with VA providers. The interview may last 15-30 minutes. During the telephone interview, the interviewer will ask questions to get your feedback on your experience with the program referring women Veterans to the program.

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

The feedback you provide during the phone interview will help us learn more about how to improve remote treatment methods for women Veterans who may be experiencing bladder leakage and/or urgency. For a complete description of benefits, refer to the Detailed Consent.

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

The most important reason to not join this study is if you are unwilling to participate in a telephone interview regarding your experience with the PURSUIT program or with referrals to the Continence Clinic. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Alayne Markland, DO, MSc, Principal Investigator, of this study at the Birmingham Veterans Affairs Medical Center (BVAMC). If you have questions,

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suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: (205) 558-7064.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn more about the usefulness of the remote delivery treatment method for treating bladder leakage in women Veterans. This treatment delivery method involves standard of care treatment that is currently used in the VA Continence Clinic. In this phase of the study, we hope to get feedback from health care providers regarding urinary incontinence screening and treatment approaches and your experience with the PURSUIT program and/or Continence Clinic.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 3 years. Your individual participation in this phase of the project will take up to 30 minutes. There will be up to 100 total provider participants enrolled to complete a telephone interview at the study's participating sites (all within VISN7).

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you agree to participate in this study, you will be asked to participate in a one-on-one, one-time telephone interview with one of our program interviewers. The interviewer will ask you open-ended questions about your experience with the PURSUIT program and/or referring women Veterans to urinary incontinence treatment.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

There is minimal risk involved with this phase of the PURSUIT study. You may experience some discomfort being asked questions about your opinion and experience with the intervention. As a participant, you can skip any questions that you prefer not to answer.

- **Photographs, audiotaping, or videotaping**
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WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You will get any direct benefits from taking part in this research study. However, your feedback will help us learn more about improving bladder leakage treatment methods for women Veterans.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

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Identifiers might be removed from the identifiable private information that is collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

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.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

There will be no cost to you to participate in the telephone interview for this VA research project.

Compensation/Payments

There will be no compensation to you for participating in the telephone interview.

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