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

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

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Abstract

The Department of Veterans Affairs Integrated Service Network (VISN-7) is our targeted region for this proposal, named “Improving Primary Care Understanding of Resources and Screening for Urinary Incontinence to Enhance Treatment (PURSUIT)” as part of the Managing Urinary Incontinence (MUI) initiative. Our overarching goal is to improve access to evidence-based nonsurgical UI treatment for women Veterans using the most effective remote delivery modality in the Southeast region of the U.S. In our first Aim, we will compare two models at the practice level: (1) the use of a practice facilitation toolkit with our mHealth UI modality alone and (2) the practice facilitation toolkit with our mHealth UI model combined with education on clinical care consultation pathways. We will employ a Type 1 Hybrid Effectiveness-Implementation design to assess the effectiveness of our mHealth intervention, while using the Reach, Efficacy/effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework to guide our practice level implementation approach. In our second Aim, we will compare patient level outcomes related to enrollment in the mHealth UI application. For our third Aim, we seek to explore women Veterans’ and providers’ perceptions of key factors that may influence future remote UI treatment scalability for national dissemination across the VHA. PURSUIT aims to target 62 practices to participate in the trial implementation that treat over 50,000 women Veterans; practices will be randomized in clusters to receive the interactive mHealth UI application non-surgical UI treatment modality with or without additional clinical UI education on clinical pathways. All primary care practices will receive practice facilitation with a PURSUIT toolkit that includes (1) 1-3visits with a practice facilitator engaging practices through virtual group sessions and one on-site visit (if allowed). (2) Mobile-health or mHealth Application Training (MAT) training: MAT training will be offered through in-person academic detailing, online resources, and ongoing support via email or office hours with project staff and experts; 3) Online Resource Hub: The online resource hub will be available throughout project implementation, and e-learning modules will serve as the structural base for virtual practice facilitation sessions; and (4) Health information technology (HIT) assistance: Project staff will offer support in screening women Veterans for UI, recruitment of women Veterans to utilize our mHealth UI model, and to refer women Veterans for additional clinical video visits. Our future goal is to disseminate the most effective modality for delivering nonsurgical UI treatment for women Veterans nationally within the Veterans Healthcare Administration.

List of Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CBOC	Community-Based Outpatient Clinic
COIN	Center of Innovation for Veteran-Centered and Value-Driven Care
GRECC	Geriatric Research, Education, and Clinical Center
HIT	Health Information Technology
ICIQ-UI SF	International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form
IDEAS	Informatics, Decision-Enhancement and Analytic Sciences
IRB	Institutional Review Board
MAT	mHealth Application Training
MHB	*MyHealtheBladder*
MHV	*MyHealtheVet*
MPI	Multiple Principal Investigator
MUI	Managing Urinary Incontinence
PFMT	Pelvic Floor Muscle Training
PSQ	Patient Satisfaction Questionnaire
PURSUIT	Improving Primary Care Understanding of Resources and Screening for Urinary Incontinence to Enhance Treatment
RE-AIM	Reach, Efficacy/effectiveness, Adoption, Implementation, and Maintenance framework
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event
SUS	System Usability Scale
UAB	University of Alabama at Birmingham
UAE	Unanticipated Adverse Event
UI	Urinary Incontinence
VHA	Veteran's Health Administration
VISN	Veterans Affairs Integrated Service Network
VVC	VA Video Connect
WH-PBRN	Women's Health Practice-Based Research Network

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2.0 Introduction

Improving primary care access to evidence-based approaches to treatment among women Veterans is an area of increasing focus within VA Health Administration (VHA).[1] Increasing numbers of women Veterans are using the VA for their general and gender-specific health care, representing a doubling in the past decade with 7% of all Veterans seen in the VHA being women. The number of women Veterans aged 50 and older is increasing within the VHA.[2] Women across the life-span and in this age range suffer from increased rates of urinary incontinence (UI).[3] Many women Veterans experience UI and may be at increased risk due to exposures during military service, such as restricted toilet access and the impact of heavy protective gear and equipment on the pelvic floor. These factors, along with known risk factors such as pregnancy, childbirth, and menopausal transitions increase UI risk among women Veterans. A recent study showed that 20 percent of women Veterans had UI.[4,5] The association of UI with post-traumatic stress and mood disorders in women Veterans returning from active service is profound and UI rates increase among women Veterans with post-traumatic stress disorder (PTSD), anxiety, and lifetime sexual assault.[4,5]

This proposed study focuses on improving access to standard of care UI treatments in primary care practiced in the VHA healthcare system for women Veterans with UI. Several evidence-based treatments are available for UI including behavioral, medical, and surgical therapies. Specifically, behavioral self-management treatments, including pelvic floor muscle training (PFMT), bladder control and voiding strategies, and fluid management, are widely recommended by consensus groups and guidelines as first-line treatment options because of their demonstrated effectiveness and low risk of side effects.[6] Persons implementing behavioral therapy for UI report greater confidence in self-management when provided with input from a clinician (physician, advanced practice provider, rehabilitation specialist) with specific training in UI management.[7] To identify gaps in UI treatment modalities within VHA, our group surveyed gynecologists, urologists, and behavioral and physical therapy providers for nonsurgical UI treatments at large VA medical centers delivering specialty care. We found that only 55% of facilities reported offering PFMT, while 14% referred to another VA, and 44% referred to non-VA care. Sixteen percent of the large facilities had no way to provide PFMT. Our data demonstrate that women Veterans have limited access to clinicians who can provide these safe and effective treatments. We proposed this study to increase access to safe, routine, standard of care behavioral treatments for urinary incontinence among women Veterans.

3.0 Objectives

Our overarching objective is to improve access to evidence-based nonsurgical, behavioral UI treatment for women Veterans using an effective remote delivery modality in the Southeast region of the U.S.

The Department of Veterans Affairs Integrated Service Network (VISN-7) is our targeted region for this proposal, named “Improving Primary Care Understanding of Resources and Screening for Urinary Incontinence to Enhance Treatment (PURSUIT)” as part of the Managing Urinary Incontinence (MUI) initiative. We will employ a Type 1 Hybrid Effectiveness-Implementation design to assess the effectiveness of our mHealth intervention, while using the Reach, Efficacy/effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework to guide our practice level implementation approach.

In this study, we will randomize clinics to one of two models: (1) our practice facilitation toolkit combined with education on existing consult pathways or (2) our practice facilitation toolkit alone.

Aim 1: In our first objective (practice level – non-research Aim), we propose an implementation strategy of practice facilitation, to improve awareness and adherence to evidence-based guidelines on nonsurgical UI treatments at the practice level. Our primary practice level outcome is the number of women screened for UI over a 6-month period. Diagnosis rates of UI and other LUTS will be a proxy measure for screening from the practice facilitation data dashboard at the clinic level.

Aim 2: For our second objective (patient level – quasi-research and clinical care Aim),. our primary patient level outcome is women who are screened for UI from the clinics who enroll in the mHealth application, MHB. Our secondary patient level outcome is women who enroll in MHB and have UI symptom improvement.

Aim 3: For our third objective (patients and providers – research Aim), we seek to explore women Veterans’ and providers’ perceptions of key factors related to the RE-AIM framework that may influence future remote UI treatment scalability for national dissemination across the VHA.

As part of the AHRQ’s MUI consortium, **PURSUIT** aims to target 62 practices to participate in the trial implementation that treat over 50,000 women Veterans; practices will be randomized in clusters to receive our practice facilitation toolkit along with the interactive mHealth UI application non-surgical UI treatment modality with or without additional education on existing clinical UI pathways.

4.0 Resources and Personnel

- The **PRIMARY** research sites for PURSUIT will be the Birmingham and Atlanta VA GRECC sites.

Site Summary Roles

Sites Collecting and Analyzing Identifiable Data:
Birmingham

Sites with access to VINCI research folder:
Atlanta, Birmingham

Additional Sites Receiving Research Dollars:
The Salt Lake City VA will adapt a currently available clinical dashboard for PURSUIT (this protocol) using CDW data. The dashboard developed for operational purposes.

Determination that Randomized Sties are Not Engaged in Research
In speaking with the Central IRB, the cIRB lead indicated that the sites randomized as part of PURSUIT are not engaged in research (see Central IRB project waiver). The implementation of PURSUIT, which was developed for quality improvement purposes, by these sites is part of clinical quality improvement. The sites engaged in research as described above are part of the evaluation/studying the process of PURSUIT implementation and the resulting impact on increasing incontinence care for women Veterans.

- Our multiple Principal Investigator (MPI) team includes **Alayne Markland, DO, MSc**, is an Associate Professor at the University of Alabama at Birmingham (UAB)/Birmingham VA Health Care System and **E. Camille Vaughan, MD, MS,** is an Associate Professor at Emory University/Atlanta VA Health Care System. As MPI, Dr. Markland and Dr. Vaughan co-direct the Birmingham/Atlanta Geriatric Research Education and Clinical Center (GRECC) and have more than 15 years of experience developing and evaluating nonsurgical UI treatments for women and men with UI. The work proposed is a natural extension of their current HSR&D-funded clinical trial at the Birmingham, Atlanta, and Durham VA sites. Both investigators also conduct in-person and remote telehealth care through their VA Continence Clinics, oversee mid-level providers who also provide care through these modalities, and oversee clinical trials related to improving access to care for women Veterans. Other leaders on the project team include: (1) **Lisa Zubkoff, PhD,** who is an Associate Professor at UAB and serves as the Birmingham/Atlanta GRECC Associate Director for Research. She is an expert in dissemination and implementation science methodology. She will lead the Birmingham VA site. She has NIH and VA funding conducting clinical research using dissemination and implementation methods, as well as mixed-methodology approaches. (2) **Andrea L. Cherrington, MD, MPH**, is a Professor in the Division of Preventive Medicine (DOPM) at UAB. Her research focuses on the prevention and management of diabetes and hypertension with a focus on health equity and community practice-based intervention; she has over a decade of expertise in intervention

development and evaluation and community-based participatory research. (3) For qualitative methodology expertise and analysis, **Beverly Williams, PhD**, is a medical sociologist and will provide support for Aim 3 to establish the interview guides, provide oversight in the coding analysis, and synthesis of the qualitative findings. (4) For biostatistical expertise, **T. Mark Beasley, PhD**, provided input into prior and current VA trials related to improving access to nonsurgical UI treatments for Veterans. He has expertise related to adaptive clinical trial designs and implementation. (5) In Atlanta, **Ursula Kelly, RN, PhD** will provide expertise related to her role as a clinician researcher and the co-director of Atlanta's Women's Health Practice-Based Research Network (WH-PBRN). (6) Also, in Atlanta, **Katharina Echt, PhD,** who has gerontology training will inform our qualitative approach and provide expertise related to the interview guides, interviews, and qualitative synthesis of our findings with Dr. Beverly Williams.

- Along with the MPI with Drs. Markland and Vaughan, along with expertise in the co-investigator team, we also involve program management support, support with clinical research coordinators, and with Advance Practice Providers who have over 10 years of experience working with the team and providing non-surgical UI treatments. The overall governance structure includes a 2-site leadership structure that parallels to our current 2-site leadership structure in the VA for the Birmingham/Atlanta GRECC. For this project, we will have weekly team calls with the project management team and bi-monthly calls with the project oversight team. Our participating operational partners include: (1) VISN-7 (regional) VHA Women's Health Leadership, **Kanini Rodney, MD, MPH**, (2) National VHA Women's Health Leadership through the Women's Health Practice-Based Research Network (WH-PBRN - Susan Frayne, MD and Diane Carney), and (3) the VA office of Connected Care within the Primary Care Service Line, and (4) Tonic for Health© platform (Parent company: Scheduling.com), providing remote patient intake, patient education, and contactless check-in using mHealth platforms among large health systems.
- For expertise in the creation and maintenance of a data dashboard, **Zachary Burningham, PhD**, joined our team and participates in PURSUIT team calls to provide input on the dashboard to focus the data provided on CBOC providers in the tri-state region (AL, GA, and SC). The dashboard is designed to provide primary care providers information about UI screening and care provided in VA settings of care to specific patients in their care panel.

Study Personnel (role)	PHI access	Recruitment of CBOCs	Practice Facilitation Toolkit Facilitator	Collection of primary and secondary outcome measures	Remote care provider	Qualitative Interviews	Data Analysis
Markland, Alayne (Multi-PI)	Yes	Yes	Yes	No	Yes	No	No
Vaughan, Camille (Multi-PI)	Yes	Yes	Yes	No	Yes	No	No
Zubkoff, Lisa (Birmingham VA Site PI)	No	No	No	No	No	No	Yes
Beasley, Mark (Co-I)	No	No	No	No	No	No	Yes
Cherrington, Andrea (Collaborator)	No	No	No	No	No	No	No
Kelly, Ursula (Collaborator)	No	Yes	Yes	No	No	No	No
Lo, Christie (Operational Partner)	Yes	No	Yes	No	Yes	No	No
Woodbury, Terri (Operational Partner)	Yes	No	Yes	No	Yes	No	No
Rodney, Kanini (Operational Partner)	No	No	Yes	No	No	No	No
Echt, Katharina (Collaborator)	No	No	No	No	No	Yes	No
Burningham, Zachary (Collaborator)	No	No	No	No	No	No	No
Phillips, Janice (Program Director)	Yes	Yes	Yes	Yes	No	No	No
Howell, Hannah (Study Manager)	Yes	No	No	Yes	No	No	No
Yoo, Steven(Atlanta Research Coordinator)	Yes	Yes	Yes	Yes	No	No	No
Boers, Johanna (Atlanta Research Coordinator)	Yes	Yes	Yes	Yes	No	No	No
Sergent, Taressa (Atlanta Research Coordinator)	Yes	Yes	Yes	Yes	No	Yes	No
Davis, Kate (Research Coordinator)	Yes	No	No	Yes	No	No	No
Adams, Katelyn (Research Coordinator)	Yes	No	No	Yes	No	No	No
Reinicke, Kayla (Practice Facilitator)	Yes	No	Yes	No	No	No	No
Khakharia, Anjali (Data Analyst)	Yes	No	No	No	No	No	Yes
Klemensen, Terry (Data Analyst)	Yes	No	No	No	No	No	Yes

- VA Contractors for this Proposal: **Tonic®** (Parent company: Scheduling.com) is an independent contractor and a registered VA Vendor who translated our intervention onto a mobile platform. The Tonic® platform can be used with iPads, iPhones, and Android devices. The system allows us to provide secure links to the program that can be used with any browser on any smartphone or computer. Moreover, Tonic's browser version dynamically resizes any survey or form, so that the patient experience is independent of screen size or type of device. This platform enables women Veterans to access the daily modules on a

mobile device (of their choice) or on the internet. Access is granted with a secure link.

- Additional VA Services for this Proposal: **Annie©** is a VA service developed by the Office of Connected Care to assist Veterans in playing an active role and focusing on their care through the VA. Annie allows Veterans to opt into their service to receive text message reminders to facilitate interaction with daily modules through Tonic ®.

  Qualtrics is a web-based platform available to VA researchers, through the Office of Research and Development, to build/send surveys or analyze/export survey responses. Qualtrics is approved to collect, process, and retain PII and PHI on 1) Veterans and dependents, 2) VA employees, and 3) Volunteers.

  MyHealtheVet is a VA service that is designed to allow Veterans to become an active partner with their health care team. MyHealtheVet will permit additional secure contact to inform individuals about UI treatment that is available to them.

- Memoranda of Understandings (MOUs) or Data Use Agreements (DUAs) for this Proposal: No MOU or DUA exists with this protocol. Our current contract will be formalized for this protocol between the Department of Veterans Affairs (participating sites) and Tonic.

5.0 Study Procedures

5.1 Study Design – Non-Research/Quality Improvement

- For this proposal, our targeted region is the VA Integrated Service Network (VISN) - 7 and includes the states of Alabama, Georgia, and South Carolina. VISN 7 encompasses an area containing eight VA medical centers and numerous outpatient clinics, called community-based outpatient clinics (CBOCs), throughout most of Alabama, Georgia and South Carolina.

  We will recruit 62 CBOCs (in clusters of 8, including 4 for Birmingham site and 4 for Atlanta site) with a goal to randomly assign 50 CBOCs over a 30-month period to receive our practice facilitation toolkit along with our standard of care mHealth UI (*MyHealtheBladder*) alone or our toolkit with mHealth UI program combined with clinical referral pathways for consultation.

Practice/CBOC Level Enrollment and Implementation Timeline

Practices for Clusters	Year 1				Year 2				Year 3			
	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Practice 1-8			○	●								
Practice 9-16				○	●							
Practice 17-24					○	●						
Practice 25-32						○	●					
Practice 33-40							○	●				
Practice 41-48								○	●			
Practice 49-54									○	●		
○ Recruitment ● 6-month close out												

- **Study Design**: Standard of Care Interventions include the (1) practice facilitation toolkit, (2) access to the mHealth UI behavioral treatment program (*MyHealtheBladder*) with or without education on (3) continence care via consult pathways.

Standard of Care Interventions:

- Practice Facilitation Toolkit (4 components) – All CBOCs will receive the practice facilitation toolkit. The toolkit has 4 components: (1) Practice Facilitation Visits, (2) Mobile-health or mHealth Application Training (MAT) training, (3) Access and education on the Data Dashboard, and (4) Health information technology (HIT) assistance. Each practice will receive 1-3 practice facilitation visits conducted virtually or in-person. All visits will involve a practice facilitator engaging CBOCs through virtual group sessions and one on-site visit (if allowed). (2) MAT training will be offered through in-person academic detailing, online resources, and ongoing support via email or office hours with project staff and experts; remote consultation with a continence care specialist will be added through the non-surgical UI mHealth modality at pre-specified randomized practice sites; (3) Data Dashboard: The online resource hub/data dashboard will be available throughout project implementation, and e-learning modules will serve as the structural base for virtual practice facilitation sessions, covering topics such as interpreting data provided about women Veterans on the dashboard, developing skills for UI screening and treatment; and access to *MyHealtheBladder*; and (4) Health information technology (HIT) assistance from the Birmingham and Atlanta study teams, along with the Salt Lake City team.

- *MyHealtheBladder* – All CBOCs will receive access to the *MyHealtheBladder* self-treatment mHealth program for women Veterans that have urinary incontinence and desire treatment via this modality. The study team in Birmingham and Atlanta will help facilitate access for the women Veterans once the CBOCs identify women with incontinence who desire treatment. As part of MyHealtheBladder, our study proposes that we use an embedded information sheet for women Veterans to "opt-in" for our study team to use their data in *MyHealtheBladder* for research purposes. Our study team uses a waiver of informed consent documentation for the individual women Veterans who are identified and use *MyHealtheBladder* to improve their urinary incontinence symptoms.
- Continence Care via Clinical Care Consultative Pathways– half of the CBOCs will be randomized to also include consultative services via a consult pathway (existing or a newly created inter-facility consult or IFC), located in Birmingham or Atlanta, to deliver the same content as *MyHealtheBladder* and assist with routine standard of care incontinence treatments for women Veterans. As part of the practice facilitation toolkit (above), CBOCs randomized to have this additional component will be provided with education on clinical pathways for routine clinical care consultation via VA Video Connect telehealth visits with a continence provider.

Process for Providing Tools to Sites that will Be Randomized.

The section below describes the assistance that will be provided to sites who are implementing the PURSUIT intervention (with or without the clinical referral pathways component) as part of their quality improvement efforts. While the processes outlined below will be provided by individuals who are on the research team, the process is part of the quality improvement implementation of PURSUIT. Names are mentioned as examples. Tasks described below may be done by members of the study team with appropriate credentials who are listed on staff study lists and have completed required research training. Additionally, the timelines outlined for the process of implementation support provided by the study team may need to be adjusted depending on the needs of the CBOCs.

Stage 1 - Pre-Implementation Preparation (Approximately 1 Month):

1) *Identify and Coach Site Champion.* It is critical that all sites have a clinical champion, typically a health care provider who is designated as the site Women's Health Provider, who will lead the efforts to promote ongoing PURSUIT education and use of *MyHealtheBladder*. The site champion will liaison with the Birmingham-based and Atlanta-based implementation teams, negotiate time for clinical staff to participate in PURSUIT activities, and help to interface with the women Veterans for screening and interest in receiving treatment for urinary incontinence. The site champion will also review the data dashboard with local staff.

2) *MAT Training and Data Dashboard Training:* Each site champion will participate in conference calls or in-person visits at baseline, 3-mo, and 6-mo, with the implementation team to guide the implementation of PURSUIT practice facilitation components. Some sites may opt to implement a select number of practice facilitation toolkit components.
3) *Obtain Baseline Data:* Using the data dashboard, our team will identify women Veterans seen at the CBOC level and identify women for targeted recruitment efforts by the baseline diagnosis of UI/LUTS rates. All practices/site champion will complete data on a form, "About Your Practice,"

Stage 2 – Launch Implementation Models:
The Birmingham team, led by Dr. Markland, will finalize a training manual for site champions to screen for urinary incontinence and offer treatments for urinary incontinence, specifically in their local CBOCs. The education materials include didactic information on tools to screen for urinary incontinence, how to engage women Veterans to use *MyHealtheBladder*, education on available VA treatment for urinary incontinence, referral for urinary incontinence treatments with specialists, and other tools and training materials needed to train staff at the CBOC. All clinical decision support tools will be accessible in CPRS and out dedicated Sharepoint site. Baseline data will be available through an existing project folder within the VA's VINCI framework on a secure VA server. Baseline data from Stage 1 will be shared with all site champions to incorporate in the initial provider education session. Additionally, if a site is randomized to receive additional information on consultation pathways, the team will coach the site champion (and clinical partner for 1:1 feedback, if applicable) in the use of the education materials to train providers in the rationale for referral for additional treatments. Using a short 20-minute, PowerPoint presentation appropriate for in-service training, a teleconference training session will be conducted to provide a structure. A certification checklist will be used to ensure all champions demonstrate competency.

Stage 3 – Continue Provider Feedback and Measurement of 3-month and 6-month Outcomes:
1) CBOC women's health providers will receive dashboard reports at baseline, 3-mo, and 6-mo for the number of women Veterans seen in clinic, number of women Veterans screened for incontinence, number of referrals for *MyHealtheBladder*, and the number of referrals for consultative visits (if randomized to this group).
2) *Provider Feedback:* In addition to the electronic dashboard reports available for the practice facilitation intervention, the champion (or clinical partner) will provide 1:1 academic detailing that includes audit and feedback with other site providers who provide care for women Veterans.
3) *Qualitative Interviews:* Site champions, providers (target recruitment for site champions/providers: 25-50total), and patients (target recruitment: 62-75 patients) will be recruited to participate in one 30-minute structured interview on perceptions of key factors that may influence future remote UI treatment scalability for national dissemination across the VHA.

4) The survey, About Your Practice, will be repeated at 6-months to monitor for CBOC level changes in staffing.

- **Minimization of Anticipated Risk**: Designated site champions and other health care providers who see women Veterans at the CBOCs will complete surveys for clinical descriptives for Aim 1, called "About Your Practice." Women Veterans who complete *MyHealtheBladder* will complete a demographics questionnaire and outcomes data questionnaires for Aim 2. The individual level data will be de-identified and will be analyzed in aggregate when possible. Loss of privacy related to incontinence treatment is a potential risk of this proposed study. All efforts will be maintained to protect and use de-identified data related to the care of women Veterans.
- **Description of the study population**
  - Site Champions – Dedicated women's health providers at the VISN-7 Medical Centers and CBOCs.
  - Health Care Providers – clinicians who provide care for women Veterans at the VISN-7 Medical Centers and CBOCs. May include physicians, advanced practice providers, nurses, social workers, and pharmacists.
  - Women Veterans – female Veterans who receive primary care visits at the VISN-7 Medical Centers and CBOCs.
- **Added protections for vulnerable populations** – VA/CBOC Employees
  - Provider-level descriptive data and outcome data (CBOC employees) will be captured and stored using a VA REDCap survey.
  - Randomization stratification will be according to the number of women Veterans assigned to individual patient-aligned care team (PACT) where each PACT may have more than one provider. CBOCs are usually smaller clinics with less providers than the PACT teams that focus solely on providing women's health and wellness. To balance these factors across randomization groups, we will use the following stratification schema:
    - Large size PACTs/CBOCs – defined as serving 500 or more women Veterans
    - Moderate size PACTs/CBOCs – defined as serving 100-499 women Veterans
    - Small size PACTs/CBOCs – defined as serving 50 to <100 women Veterans

5.2 Recruitment Methods

- Practice level - We plan to engage Medical Centers (WH PACTs and primary care PACTs) and CBOCs that serve at least 50 women Veterans with primary care services (practice sites = 62). These CBOCs will be

recruited through connections with each locally identified women's health providers and other health providers who provide care to women Veterans. We anticipate recruiting 62-100 providers across the 62 CBOCs with a goal to recruit at least 50 practices.

Practice recruitment (Table above): In VISN-7, we will recruit primary care practices that serve at least 50 women Veterans. Recruitment will start in the third quarter of year 1. A total of 8 practices will be recruited with each wave – 4 by the Birmingham site and 4 by the Atlanta site. These 8 sites will be followed for 6 months with rolling recruitment, adding 8 additional sites per quarter to reach our goal of 50 total practices. For recruitment to begin, we will conduct an informational meeting (onsite or remotely) to further explain the study objectives and procedures with the designated women's health practice consultant. Per VHA guidelines, all CBOCs have a designated women's health practice consultant. Then, the practice facilitators will meet one on one with the site champion for each practice at the CBOC.

- Patient level Screening and Enrollment in MyHealtheBladder– With permission from the providers who evaluate and treat women Veterans, we can send letters directly to women Veterans at each VISN-7 primary care clinics (Medical Centers/PACTs and CBOCs) and inform them about the ability to receive nonsurgical UI treatments with our mHealth application (Aim 2), *MyHealtheBladder*. We estimate that we can target 50,000 women Veterans at 50 CBOCs. From this catchment area, we estimate that 30% of the women (n=15,000) will have UI symptoms. From this number, we anticipate that 35% of the women Veterans will participate (n=2500) in screening and increase in UI/LUTS diagnosis rates.
    - The Corporate Data Warehouse (CDW) houses the majority of patient-level information within the VHA. Data are collected across a variety of relational databases and updated on a daily basis. The CDW databases will be used to obtain contact information of women Veterans, with primary care visits in a VISN-7, for recruitment efforts. Our team will submit a DART request for acquisition of this data.
    - Approximately 60-75 women Veterans who participated in Aim 2 and agreed at that time to be contacted for a qualitative interview, will be invited to participate in a phone interview.
- Recruitment Materials: Emails and telephone calls will be used to recruit providers at the CBOCs who evaluate and treat women Veterans. Presentations about the study will also be coordinated at the VISN level through the women's health provider groups. Letters will be mailed to women Veterans with permission from the CBOC providers for local recruitment. Emails will also be sent to women Veterans through MyHealtheVet (VA online patient portal). Additionally, with permission of the CBOC providers, we will provide an informational study flyer and

brochure for display and/or distribution at the respective CBOC location. We will also send messages through the patient portal, MyHealtheVet.

- Participant Payments: Women Veterans who enroll and start using *MyHealtheBladder* will receive $50 in compensation via a check or direct deposit through the current participant payment processes at the Birmingham and Atlanta VA research offices. A $25 payment will be provided at baseline completion and a $25 payment at 8-week completion.
    - Additionally, women Veterans who participate in a qualitative interview (Aim 3) will receive $20 in compensation via a check or direct deposit.

5.3 Informed Consent Procedures

- Aim 1: We are requesting a waiver of informed consent for providers who receive the practice facilitation components for this study. The practice facilitation phase (Aim 1) is non-research.
- Aim 2: We are requesting a waiver of HIPAA Authorization for screening and recruitment purposes of women Veterans who receive care at VISN-7 CBOCs.

  We are requesting a waiver of documentation of informed consent for patients/women Veterans for this study. We will embed an information sheet in *MyHealtheBladder* for women Veterans to "opt-in" to having their data used for additional data analysis. As needed, we will obtain HIPAA Authorization, via the VA-approved DocuSign platform, from patients for study compensation purposes.
- Aim 3: We will obtain written informed consent for the patient (ICF) and provider (ICF in development and to be submitted for IRB approval prior to implementation of Aim 3) qualitative interviews, via the VA-approved DocuSign platform. The research study coordinators will obtain informed consent prior to the qualitative interviews. No consent will be obtained from authorized representatives for this study. We will also request a waiver of HIPAA authorization for the patient and provider qualitative interviews. No PHI will be collected during these interviews and patient participants in this Aim will have already consented and participated in Aim 2.

- All study personnel will be trained regarding human subjects protections requirements and how to obtain and document informed consent.

5.4 Inclusion/Exclusion Criteria

- Study eligibility criteria are in Table 3. We will recruit 15,000 women Veterans who provide informed consent, aged 20 and older.
- A diagnosis of UI, including all types of UI (stress UI, urgency UI, and mixed UI) is required for inclusion. Women who are currently pregnant will be excluded until they are at least 12-weeks post-partum. We will also exclude women Veterans who have no access to a telephone (will provide access to the internet and a tablet device when needed), or cannot speak English.

Table 3: Inclusion and Exclusion Criteria

Inclusion criteria: • Female • Veteran • 20 years old or above • Diagnosis of UI (all types) • Access to internet via mobile device or computer
Exclusion criteria: • Non-Veteran • Currently pregnant or less than 12 weeks postpartum • Non-community dwelling • Non-English speaking

5.5 Study Evaluations

In summary, the study evaluation will begin by identifying baseline characteristics of the CBOC and the providers, as well as the patients, that may impact implementation. This will be measured at Baseline by 1)an "About Your Practice" survey; 2) monitoring of the implementation process through meetings with a clinical champion at baseline, 3-months, and 6-months to give feedback on women being screened and diagnosed with UI, as well as consults placed; 3) monitoring of implementation progress for the women who are screened and then enroll in MHB; and 4) qualitative interviews addressing implementation factors suggested by the 6 months following initial implementation of PURSUIT.

Steps in the Evaluation Process for Clinic Level Data

1. **Collection of Baseline Characteristics that may impact implementation**. The sites will be asked to identify all individuals directly involved in the planning and execution of implementing PURSUIT (e.g., clinical champions, providers, and other staff). These sites will be asked to complete a baseline site information document, About Your Practice (1 survey report per site/medical center completed via the VA REDCap system) that will collect information on clinical team members, processes, and size and composition of the CBOC and impacted clinical services, as well as identify additional providers and staff potentially impacted by the implementation.
2. **Quarterly Monitoring of Process/Workflow of Implementation**. At the start of the implementation, the research team will send written site-level questions to the Site Clinical Champions to fill out on behalf of their respective site's core implementation team. The purpose is to establish baseline information on the process of implementing the PURSUIT practice facilitation intervention model (depending on the study arm). Additionally, we will collect baseline information on the organization of women's health services at each CBOC. Components of the workflow process will then be stored in a Microsoft Excel or Word spreadsheet to be sent to the sites for updates approximately every three months. We will pull data from Corporate Data Warehouse on the number women empaneled at the CBOC, as well as some basic demographics (age, race/ethnicity, and BMI). No individual patient level data will be collected at the CBOCs.

3. **Monitoring of Implementation – Implementation Progress**. We will also measure the degree of implementation and barriers and facilitators of implementation process through approximately every 3 months after baseline and 6-months with facility-level reports from the data dashboard (monitoring provider engagement, diagnosis rates, and consults placed).
4. **Evaluation of the Implementation Process – Qualitative Interviews.** At approximately 6 months following the start of the implementation process at each of the sites, we will conduct semi-structured qualitative telephone interviews with one member of the core implementation team at each site to assess factors suggestive of implementation success. The goal will be to interview the same individuals interviewed at Baseline. The questions composing the qualitative interview guide will depend upon the formative evaluation. As such, the guide will be developed after the initial implementation and approved by the IRB prior to use, see attached.

Evaluation Process for Patient Level Data

1. Self-Enrollment into MyHealtheBladder – This is the number women who complete the baseline data and enroll in the MHB program.
2. UI Symptom Severity - We will evaluate effectiveness of our two models using questionnaires embedded within *MyHealtheBladder*. For UI severity, we embedded the validated International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF) for the patient-centered primary outcome measure based on psychometric properties and use in other studies using similar interventions.
3. Adherence - We also propose to study program adherence and have embedded questionnaires on adherence to our behavioral treatments, specifically pelvic floor muscle exercise adherence.
4. Usability and Satisfaction - We embedded several questionnaires within the intervention, including usability with the System Usability Scale (SUS)[70] and satisfaction with program (Patient Satisfaction Questionnaire and General Impression of Improvement, PGII Questionnaire).
5. Other patient level covariates include demographic variables, such as age, education, marital status, and race/ethnicity, medical and mental health conditions, and medication usage.
6. Qualitative Interviews – Approximately 1-4 weeks after completion of the MHB program sessions, some patient participants will be invited to participate in a semi-structured telephone interview with one member of the core implementation team at each site to assess factors related to program satisfaction and adherence.

Data Collection	Outcome	Instrument	(Collected from) Administration Timepoint	Length of time
Primary Outcome	Diagnosis rates of UI/LUTS	Data dashboard	*(Clinic/Provider)* Change in diagnosis rate from Baseline and 6 months post-Baseline	N/A
Other Outcomes	Adoption rates of the provider toolkit	Data dashboard	*(Clinic/Provider)* Change in usage from Baseline and 6 months post-Baseline	N/A
	Enrollment rates of women Veterans for MHB	Qualtrics	*(Patient-Primary)* 3-and 6-months post-Baseline	N/A
	Site information & Workflow	7-item "About Your Practice" survey	*(Provider)* Baseline and 6-months post-Baseline	15-30 minutes
	Demographics & Health History	11-item form in Tonic (MHB)	*(Patient)* Baseline	5-7 minutes
	Symptom Improvement	4-item ICIQ-UI SF in Tonic (MHB)	*(Patient)* Baseline, 2-months post-Baseline, 3-months post-Baseline	2-3 minutes
	Adherence	2-item PFME adherence	*(Patient)* 7-, 21-, 35-, and 42-days post-Baseline, 2-months post-Baseline, and 3-months post-Baseline	1-2 minutes
	Usability	10-item SUS	*(Patient)* 2-months post-Baseline	4-5 minutes
	Treatment	7-item Treatment Follow-up in Tonic (MHB)	*(Patient)* 3-months post-Baseline	1-2 minutes
	Satisfaction and Perception of Improvement	3-item PSQ, PGI-I, and EPI	*(Patient)* 2-months post-Baseline, 3-months post-Baseline	2-3 minutes
	PFM and Bladder Diary Assessment	8-item (total)	*(Patient)* Day 3 (6 items), 30 (1 item), and 54 (1 item) post-Baseline	2-3 minutes

5.6 Data Management

- **REDCap**: VA REDCap is a free, secure VA application approved for storage of PHI and PII. Provider- and patient-level data will be stored in REDCap for recruitment and status tracking, as well outcomes data management.

  Only approved study staff will have access to data stored in REDCap and user permissions can limit access between different sites' data within multi-site studies.

- **VA Informatics and Computing Infrastructure (VINCI)**: The VA Informatics and Computing Infrastructure (VINCI) is a Department of Veterans Affairs (VA) Health Services Research & Development (HSR&D)

resource center that provides a secure, central analytic platform for performing research and supporting clinical operations activities. It is a partnership between the VA Office of Information Technology (OI&T) and the Veterans Health Administration Office of Research and Development (VHA ORD). VINCI includes a cluster of servers for securely hosting suites of databases integrated from select national VA data sources. It will be used by our team for acquisition and access to CDW data.

VA-credentialed research staffs are granted access to study-specific data along with tools for analysis and reporting in the secure, virtual working environment through a certified VHA network computer within the VA.

Data Storage Locations

- **REDCap** and **VINCI** (e.g., CDW) data is housed on VINCI servers located at the Austin Information Technology Center, 1615 Woodward St., Austin, TX 78772-0001.
- **VA Network Shared Drive:** A collaborative VA network shared drive has been created for this multi-site study. Only VA-credentialed research staff will have access to this shared drive. Study data downloaded from the VINCI environment, Qualtrics, and Tonic (MyHealtheBladder) will be stored on this drive before uploading to REDCap.

5.7 Data Analysis

- For the provider-level outcome (primary outcome), we will measure the diagnosis rate of UI/LUTS at baseline, 3-mo, and 6-mo to evaluate the changes over time. This This measure will be collected through the team at the Salt Lake City VA using the CDW data on the data dashboard.
- For the patient level outcomes (secondary outcome), we will evaluate screening and enrollment outcomes, as well as engagement with , *MyHealtheBladder*.
    - Enrollment rates in MyHealtheBladder will be defined from the women screen who complete the baseline data
    - For UI severity, we embedded the validated International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF) for the patient-centered primary outcome measure based on psychometric properties and use in other studies using similar interventions.[8,9,10,11] Specifically, we will use the minimally important clinical difference (ICIQ-UI Short Form, Range is 0-21 and MICD is 2.52 (SD 2.56)) to measure improvement in UI severity.

      Participant demographics, medication usage, and health history will be collected using instrument currently in use for the PRACTICAL study and be analyzed as covariates.

- We will measure the patients' adherence to the pelvic muscle exercise guidance provided through the *MyHealtheBladder* program using a 2-item instrument (secondary patient level outcome)
- For system usability (secondary patient level outcome), we will use the 10-item System Usability Scale (SUS).[12] Patient responses are on a 5-point Likert scale from "Strongly Disagree" to "Strongly Agree." The SUS has a score range of 0 to 100. The general guideline for interpreting the SUS score is: ≥ 68 = "Above Average"; <68 = "Below Average." = "Excellent."
- We will use the following questionnaires to measure patient satisfaction and global improvement. One question will inquire about patient satisfaction (Patient Satisfaction Question (PSQ)), one will address patient impression of improvement (Patient Global Impression of Improvement (PGI-I)[13]), and one will have the patients estimate their improvement on a scale from 0-100% (Patient Estimated Percent Improvement (EPI)).

- Data will be analyzed using de-identified data from REDCap databases for provider and patient-level data sources. The study biostatistician will analyze the data on a VA server behind the VA firewall.
- Randomization design is based on stratification as in section 5.1
- Clustering is done for clinics by site per the table in section 5.1
- Sample size considerations are based on a cluster analysis[14] by the number of clinics. Our recruitment goal is to recruit and randomize 50 clinics to each group (n=25 per group). Assuming an unequal number of women Veterans (patients) in each group according to cluster, we would have 80% power (alpha level = 0.05 and an ICC of 0.05 for each group) to detect changes in diagnosis rates of UI/LUTS between randomization groups in our primary provider level outcome..
- See **Appendix 1** for power calculation table.
- AHRQ has contracted the RAND organization to evaluate each grantee within the MUI consortium. Aggregate data will be sent to RAND for evaluation quarterly. No PHI/PII or identifying information will be shared outside of the program team. All aggregate data will be reviewed by the Privacy Officer prior to being sent outside of the VA to ensure data being shared does not pose any privacy concerns. A copy of the evaluation done by RAND will be returned to VA investigators. VA investigators will be allowed to review and approve prior to publication.

5.8 Withdrawal of Subjects

- CBOCs, providers, and patients can withdraw from study participation at any timepoint during the study progress.

- If a site, a provider, or a patient decides to stop participation (withdraw), no further data will be collected, and communication will cease from the study team. If patient desire additional treatments after withdrawal from *MyHealtheBladder*, this information will be communicated with the treating provider at the CBOC.

6.0 Reporting

The Multi-PIs will make determinations on unanticipated adverse events.

Serious Adverse Events (SAE) are:

- A serious adverse event is defined to include any adverse experience that results in the following:
    - Death
    - Life Threatening
    - Hospitalization – initial or prolonging
    - Persistent or significant disability or incapacity
    - Medical event that may jeopardize the subject and require medical or surgical intervention to prevent permanent outcome

Documentation

Multi-PIs will make determinations if SAE is related, probably related, not related or unable to determine. Any local research death that is unanticipated and related to the research must be reported orally to IRB immediately. Within 5 business days of becoming aware of an event, the study team must provide a written report utilizing the SAE Reporting Form.

All local adverse events (expected, unexpected, related or not related), serious adverse events, protocol deviations, and safety reports, are to be recorded by the investigator in their study documents at the time of the event, and summarized in a spreadsheet/table format to be turned in at the time of continuing review or study closure.

Research coordinators will follow local VA site policies regarding documenting and submitted adverse event forms. Birmingham Lead Site should made aware and given IRB documentation for ALL UAE's and SAE's.

7.0 Privacy and Confidentiality

Item 1.1: In this protocol, we outline the privacy requirements for the protection of the research subjects (women Veterans who agree to receive standard of care treatment for their urinary incontinence and providers who agree to have qualitative interviews). We also describe clinical care data and research data that we use in this protocol. Clinical care detail will be used for the practice facilitation approach (non-research). We are using research data collected through *MyHealtheBladder* for women Veterans and for the research data we collect with detailed qualitative interviews.

Item 1.2: Our data usage with the mobile health application called *MyHealtheBladder* is described in our contract with the approved VA vendor, Tonic/Scheduling.com/R1RCM (non-VA entity). All data collected on this platform will be de-identified and used clinical care purposes within the VA and is VA data. The non-VA entity will not have access to this clinical data. The VA data will be saved in a protected database, REDCap, on the VA-approved server at all times. The qualitative interviews will be audio-recorded on a VA-approved device and transcribed by the VA-approved transcription services.

Items 1.3, 1.4, and 1.5: For this protocol, we are waiving the HIPAA authorization for recruitment purposes and for the providers who will be educated on the ability to treat women Veterans with urinary incontinence as proposed in this protocol. We also requested a waiver of consent documentation and HIPAA authorization documentation to pay the women Veterans who elect to receive treatment with *MyHealtheBladder*. We will also obtain a written consent and waiver of HIPAA authorization for the women Veterans and the providers who agree to have a phone interview for the qualitative analysis. No PHI/PII will be disclosed to a non-VA entity and a detailed contract will be approved for this protocol.

Item 1.6: Women using the bladder mobile health app, *MyHealtheBladder*, will sign a HIPAA authorization for their data to be used for payment purposes (if required per IRB determination). We are requesting a waiver of written HIPAA authorization for Aim 3 (qualitative interviews) this protocol. All other data obtained through *MyHealtheBladder* will be de-identified and analyzed in aggregate for clinical purposes and not for research purposes. This is consistent with VHA Directive 1605.1, Appendix A.

Item 1.7: No biospecimens will be collected for this protocol.

Item 2: We requested a waiver of written consent for the providers that are receiving the practice facilitation model in this protocol (non-research). For women Veterans who chose to complete treatment via *MyHealtheBladder*, we are requesting a waiver

of documented consent and will obtain a signed, written research HIPAA authorization. For the providers and women Veterans who agree to have recorded interviews, we will obtain a written research informed consent form but will request a waiver of HIPAA Authorization for this study activity; the interview guide does not include questions related to PHI/PII.

Item 3: We are submitting a request for waiver of HIPAA authorization to access PHI for recruitment purposes. The request to obtain names and addresses of women Veterans seen at the participating CBOCs will be obtained for recruitment purpose. Providers will agree to sign recruitment letters (see attached recruitment letter). We are waiving HIPAA authorization for names/addresses since this PHI poses no more than minimal risk to the privacy of the research participants (all women Veterans will receive a letter). We would not be able to target women Veterans without this recruitment plan given that many women do not discuss urinary incontinence with providers but may want to seek available treatments. Likewise, many providers may not be familiar with available treatments for urinary incontinence and care may not be provided directly through routine clinical care. This research would not be able to be conducted without this waiver and access to PHI to send letters. We are only using names and addresses as PHI in this waiver of HIPAA request. With assistance from data analysts at the Atlanta VA, we will be able to access data for this request through the CDW.

7.0 Communication Plan

The MPIs and Birmingham and Atlanta VAMC study staff will obtain local site approval from their respective site IRB. The CBOC facilities will not require IRB approval as their involvement is considered quality improvement and only the Birmingham and Atlanta study teams will be involved in research data collection and management.

Birmingham and Atlanta Study Team Meetings:

The Multi-PIs will conduct weekly meetings with the VA research team members. These team meetings will take place via Zoom.

The conference call will include:

- Announcements that affect all sites.
- Each site will report on their recruitment activity from the last conference call and any issues that affect their site.

- The Birmingham Project Manager will run a recruitment report of each site's recruitment numbers prior to each team meeting.

- Any changes to IRB documentation, informed consent, study intervention, data collection & management, and safety reporting will be discussed on the conference call.

- All changes will be documented in a decision log on the study's secure VA shared drive by the Birmingham Project Manager. The Birmingham and Atlanta study personnel have access to this folder. The Birmingham Project Manager will also share updated documents with other study collaborators and operational managers via email.

CBOC Site Leadership and VA Research Team Meeting:

- The Multi-PIs and Birmingham and Atlanta VA research team members will meet, in-person or via Microsoft Teams/Zoom, with the CBOC site leader (ex: Women's health consultant) every 3 months and as requested during the initial 6-month practice facilitation phase of the study at each respective CBOC site.

Records Management

The VA Federal records associated with this study will be maintained and dispositioned in accordance with Records Control Schedule 10-1 (RCS 10-1).

8.0 References

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Appendix 1: Power Calculation

		Group One						Group Two											
alpha (α)	d	SD_G	N_G	N Units	M_G	ρ_G	D_G	SD_C	N_C	N Units	M_C	ρ_C	D_C	Dem1	Dem2	Dx	Z(α/2)	Power (1-β)	
0.05	0.1889	1	3500	25	140	0.05	7.95	1	3500	25	140	0.05	7.95	0.002	0.002	2.80	-1.959964	0.800295	Equal
0.05	0.1889	1	3500	25		0.05	9.05164	1	3500	25		0.05	8.63901	0.003	0.002	2.7	-1.959964	0.757115	Unequal
0.05	0.1992	1	3500	25		0.05	9.05164	1	3500	25		0.05	8.63901	0.003	0.002	2.80	-1.959964	0.800086	Unequal

Legend	
alpha (α)	Significance Level
d	Mean Differerence
SD_G	Standard Deviation for Group 1
N_G	Sample Size for Group 1
N Units	Number of Clusters for Group 1
M_g	Average Cluster Size for Group 1
ρ_G	Intra-Class Correlation for Group 1
D_c	Design Effect for Group 1
SD_C	Standard Deviation for Group 2
N_C	Sample Size for Group 2
N Units	Number of Clusters for Group 2
M_c	Average Cluster Size for Group 2
ρ_C	Intra-Class Correlation for Group 2
D_c	Design Effect for Group 2

Department of Veterans Affairs

RESEARCH INFORMATION SHEET

Version Date: 2/6/2024

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

Principal Investigators: Lisa Zubkoff, PhD, and Alayne Markland, DO, MSc

VA Facilities: Birmingham and Atlanta Sponsor: Agency for Healthcare Research and Quality (AHRQ)

KEY SUMMARY INFORMATION ABOUT THIS STUDY

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 about improving access to non-surgical bladder leakage, or urinary incontinence (UI), treatment for women Veterans. It is being funded by Agency for Healthcare Research and Quality (AHRQ). By doing this study, we hope to learn the best way to deliver remote non-surgical treatment to women Veterans with bladder symptoms.

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

Your participation in this research will last about 3 months. During this time, you will receive standard of care from an online educational program called ***MyHealtheBladder***. You will review educational sessions on a weekly basis for 8 weeks and will be asked to complete a follow-up survey 12-weeks after enrollment. Throughout the study, you will be asked to answer questions online related to your health, bladder leakage, and track your behavioral training. When you complete the intervention, you may be asked if you would like to participate in an interview about your experience. You do not have to participate in the interview, if you do not want to.

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

The most important reason to join this study is that your bladder leakage may improve.

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

The most important reason not to join this study is if you are not willing to receive treatment for bladder leakage via remote delivery.

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

There are no known health risks associated with this study. Possible risks of participation are loss of confidentiality or discomfort or fatigue from completing study questionnaires. If, for any reason, you wish not to answer specific questions, you will be able to do so.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include improved bladder leakage symptoms and being enrolled in a remote treatment option not normally offered by the VA.

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

You may choose not to participate in this study. If this is your decision, there are other choices such as behavioral treatment, medication, and surgical treatment. You may discuss these options with your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Study data will be stripped of all patient 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 by approved study team personnel. Electronic records will be maintained through the Veterans Administration Computerized Patient Record System (CPRS), a secure, password-protected network.

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.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Participation in this study is voluntary and you may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. Stopping the study will in no way affect or threaten the quality of care you receive now or in the future or your opportunity to participate in future studies. If you would like to withdraw, please let your personal doctor or the Birmingham VA research team (205-558-7067) know. You may also be withdrawn without your consent for medical or other reasons if your personal doctor, or the study doctors, believe it is in your best interest for medical or other reasons or if you do not follow study instructions.

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

There will be no cost to you for taking part in this study.

Compensation/Payments

You will receive a total payment of $50 for completing the MyHealtheBladder program ($25 for completing the baseline assessment and $25 for completing the 8-week assessment). If you participate in an optional telephone interview, you will receive an additional $20.

RE-CONTACT

The final stage of this study involves 30-minute telephone interviews with participants. These interviews are optional. If you are interested in participating in a one-time interview, please indicate on the “opt in” form if you are willing to be contacted about this future stage of the study. If you agree to be re-contacted, you will receive a research study consent form for review and signature prior to participating in a telephone interview.

I agree to be contacted about the one-time, optional telephone interview.

- o Yes
- o No

TEXT MESSAGE REMINDERS

(Optional) If you are interested in receiving weekly text message reminders about the program's educational modules, your contact information will be entered into **Annie**, a service developed by the VA. This is an optional service and is not a requirement to participate in the program.

- Annie messages are automated and not monitored by the health care team.
- Annie is not the right place to ask for help, rather patients should contact their health care teams directly with health concerns.
- SMS text messages are not secure and there may be costs associated with sending and receiving texts.
- Collection of patient's info by Annie is subject to federal law.
- Sending Start and Stop begins and ends program participation.

By selecting "Yes" below, I voluntarily agree to receive secure text message reminders to my personal phone using **Annie**, a VA-created service. *Standard text message rates apply*.

- o Yes
- o No

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Alayne Markland of the Birmingham VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: (205) 558-7067.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

By selecting "Yes" below on this web-based platform (Qualtrics), I voluntarily consent to participate in this study.

- o Yes
- o No