Protocol

"Perioperative Post-Prostatectomy Incontinence Home Telehealth Program"

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SPECIFIC AIMS

Prostate cancer affects 1 in 6 men in the United States.[1] Prostate cancer treatment, particularly radical prostatectomy, results in persistent incontinence that in patient surveys is significant enough to require pads in 1of 3 of men undergoing surgery.[2] However, there are several randomized, controlled trials of perioperative pelvic floor muscle training, including our own work,[3] demonstrating clinically and statistically significant improvement in post-prostatectomy bladder control.[3-8] Despite this strong evidence, most men undergoing radical prostatectomies do not receive pelvic floor muscle training. Preoperatively, men are counseled about the probability of incontinence and its usual course which is to improve and then resolve. They are discharged from the hospital with a urinary catheter. One to two weeks after surgery their catheter is removed during a clinic visit, the urine begins to drip out, they are reassured it is temporary, and they may be briefly verbally instructed in pelvic floor muscle exercises. However, they receive no formal pelvic floor muscle training. One barrier to translation of pelvic floor rehabilitation into urology practices, including those in the VA, is the lack of therapists or other interventionists with expertise in pelvic floor muscle training. Rather than training sufficient numbers of therapists VA-wide, a more cost-effective approach could be a telehealth-administered perioperative pelvic floor muscle training program.

Telehealth is the use of medical information exchanged from one site to another via electronic communications to improve patients' health status. Telehealth has been shown to be an effective means to deliver care to Veterans in rural settings or in VA Medical Centers without expertise in specific disciplines. The VA Care Coordination Home Telehealth (CCHT) Program has been highly successful with implementing patient education and monitoring programs for a wide variety of chronic as well as subacute conditions with over 300,000 Veterans receiving care through CCHT in FY2010.[14] Although most of the clinical trials of perioperative pelvic floor muscle training involved in-clinic training, a randomized controlled trial[11] and our own work outlined in the preliminary studies section, have demonstrated the effectiveness of a written program of pelvic floor muscle training, supplemented with initial in-person contact.

We are proposing to use home messaging units and telehealth as the means to deliver an evidence-based perioperative protocol of pelvic floor muscle training directly to Veterans in their homes. This would enable all Veterans undergoing radical prostatectomy to benefit from this training. Our perioperative program has already been developed and pilot tested in our VA Rehabilitation R&D-funded study (F6938R) Perioperative Telehealth Program for Post-Prostatectomy Incontinence. The program was highly rated by Veteran participants undergoing radical prostatectomy. The next step in this line of research is to test the efficacy of the perioperative rehabilitation program in a randomized, controlled trial.

- The **primary objective** of our proposed randomized, controlled trial is to demonstrate the effectiveness of a telehealth-administered, evidence-based perioperative rehabilitation program for Veterans undergoing prostate cancer surgery to reduce post-prostatectomy incontinence and improve quality of life compared to current care.
- The **hypothesis** to be tested is that a telehealth-administered, evidence-based, perioperative rehabilitation program including education, pelvic floor muscle training, progressive exercises, and bladder control techniques will be effective in reducing post-operative incontinence compared with current care.

The primary outcome measure will be time to continence following surgery based on the International Consultation on Incontinence Questionnaire Short-Form (ICIQ-SF), a brief, reliable questionnaire that has been validated in men and shown sensitivity to change with treatment in men with post-prostatectomy incontinence.[24,26] Time to continence is extremely important to the Veteran who wants to recover bladder control as soon as possible after surgery, and is the outcome in most clinical trials in this population. Secondary outcome measures include: total score on the Urinary Incontinence Subscale of the Expanded Prostate Cancer Index Composite (EPIC), a validated health-related quality of life tool specific to prostate cancer survivors,[30] pad use as measured by the EPIC, the Incontinence Impact Questionnaire Short Form,[35] the International Prostate Symptom Score Quality of Life Question,[36] and three validated global patient ratings: the Estimated Percent Improvement, the Global Perception of Improvement, and the Patient Satisfaction Question.[34] All outcome measures will be obtained using the telehealth program. The current care group will

also receive the telehealth program, but without the pelvic floor muscle training component to control the use of technology.

If proven efficacious, the program could be rapidly disseminated across VA through the Care Coordination Home Telehealth Program so that all Veterans undergoing radical prostatectomy can have evidenced-based perioperative pelvic floor muscle training and improved continence outcomes.

RESEARCH STRATEGY

OVERVIEW

This will be a randomized controlled trial of telehealth administration of an evidence-based perioperative pelvic floor muscle training program versus an attention control condition to reduce the severity and duration of post-prostatectomy urinary incontinence. The primary outcome will be time to continence (date of surgery until no leakage reported for 3 weeks in a row). Related symptoms, severity of incontinence, condition-specific quality of life, and patient assessment of outcome and satisfaction will be measured as secondary outcomes. The telehealth program was developed and pilot tested with RR&D grant funding and was well accepted by Veterans. The telehealth device used in the pilot study was a Health Buddy™ (Bosch Inc. – Figure 4) which is used widely throughout the VA in the Care Coordination / Home Telehealth (CCHT) program.[11] Bosch is exiting the telehealth industry as of May 15, 2015 but has agreed to follow research participants currently in the program until March 15, 2016. The program, with the branching logic will be transferred to similar technology with another VA approved telehealth vendor. One of the advantages of telehealth programs is the capability to have branching logic, so that the program is individualized depending on the progress and symptoms of the Veteran as he is progressing through each day's session.

The control group is designed to control for the daily use of a telehealth program (an attention control) as well to equate basic information about urinary incontinence between groups. The control program matches the number of interactions but is limited to general prostate cancer information; perioperative care; wetness, odor and skin care management but no content on pelvic floor muscle training and bladder control strategies. Outcome measures will be administered by the telehealth program in both groups. For the Health Buddy, data are stored on the telehealth program and transmitted each night via toll-free telephone lines to a database behind a secure VA firewall as they are in the CCHT program. This was proven to be feasible and practical in our pilot study. For the web-based program, the data will be stored on a secure website with VA-approved encryption. Both groups will have use of the telehealth program monitored and quantitated. Preoperatively and 2 months postoperatively, telehealth sessions will be daily. After 2 months postoperatively, both groups will log-in weekly for outcomes measurement until 6 months postoperatively and two more times at 9 & 12 months postoperatively. If we cannot obtain a response through the telehealth program, the questionnaires will be mailed to the participants along with a postage-paid return envelope. These measures are delineated in detail in the Outcome Measures section and in Table 5. The telehealth content for each session for both groups ends with a "fun fact" including sports and other trivia, famous men who have done well after prostate cancer diagnosis, etc. which have been successfully implemented in the pilot study and promoted adherence to the daily home telehealth program, in our pilot study as well as in the CCHT programs VA wide. At 12 months, Veterans still incontinent in both groups will be offered treatment in the GRECC Continence Clinics or the VA Urology Clinic.

THEORETICAL FOUNDATION

The major theoretical underpinnings for this proposal are drawn from the Health Belief Model (**Table 1**), which describes four factors influencing health efforts, adherence and a person's readiness to take action: perceived threats, benefits, barriers and cues to action.[22] Developed to improve adherence among TB patients, the Health Belief Model is ideally suited to management of post-prostatectomy incontinence. Both conditions are associated with stigma in those affected, can be treated with resulting cure in many of those affected, can become a chronic condition in others, and require daily adherence to therapy to improve the probability of cure or control. The daily interaction with the telehealth curriculum should prompt the participant to take the steps necessary to increase the probability of recovering continence. Telehealth technology is extremely well suited to provide education on the health problem, and to guide patients in their rehabilitation program with daily interaction, thus increasing adherence. Patients who encounter barriers with the telehealth curriculum as guidance will trigger calls from the monitoring center to problem solve through telephone contact with a nurse practitioner skilled in management of post-prostatectomy incontinence. Telehealth is not the intervention, but

a means to administer the intervention, which is an evidence-based set of skills to improve pelvic floor strength and bladder control. **Table 1** outlines the application of the concepts of the Health Belief Model in the design of this proposal.

Table 1 - Health Belief Model[22] Applied to Telehealth-Administered Perioperative Rehabilitation Program for Patients Undergoing Radical Prostatectomy

Concept	Application
Perceived Susceptibility/ Severity	Patients considering radical prostatectomy for treatment of prostate cancer often do not completely comprehend the risk of postoperative urinary incontinence, despite a thorough explanation by their urologist. The education provided preoperatively through the telehealth program will increase awareness of susceptibility to and consequences of incontinence, but even more importantly will focus them on an action plan with the potential to decrease the severity of postoperative incontinence. This rehabilitation program will be started preoperatively and continues when they are free from postoperative discomfort.
Perceived Benefits	The telehealth-administered curriculum will reinforce the urologist's discussion of the probability of postoperative incontinence, lessening the possibility of patients believing that they were not fully informed when they confront the realities of loss of bladder control postoperatively. The telehealth curriculum will educate the patient about the demonstrated benefit of the evidence-based, perioperative rehabilitation program in terms of reduction in severity and duration of incontinence. It will specify how, where and when to take action and set expectations about potential benefits.
Perceived Barriers	Preoperatively, when not incontinent, many patients have trouble overcoming the barriers to initiating a rehabilitation program and integrating it with daily routines. The telehealth program, with its educational program and its daily prompting can help overcome these barriers. Postoperatively, when confronted with leakage, patients will be prompted to participate in a step-by-step program to decrease their leakage. The nature of stress urinary incontinence with variability leakage volume depending on activity can lead to days with more leakage, which could discourage the Veteran and cause abandonment of the rehabilitation program. This is best counteracted in clinic with frequent contact with a therapist, and daily interaction with the telehealth program will serve in this role, with back-up by a nurse practitioner if needed as determined by the Veterans answers to the telehealth administered questions or by lack of daily use of the program.
Cues to Action	The telehealth curriculum will serve to provide information, promote awareness and remind or cue the participant to action on a daily basis. The branching logic of the system allows customization of the rehabilitation program depending on individual barriers and progress.
Self-Efficacy	While our data establish the usability of the intervention, confidence in one's ability to engage, adhere and gain benefit from the intervention will be supported by providing training and support, the reinforcing motivational aspects of the intervention, and feedback specific to goal attainment/ progress to foster confidence.

METHODS

Overview and Timeline

The overall timeline is shown in **Table 2**.

Table 2 – Project Timetable

Activities	Year 1				Year 2				Year 3				Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Convert Placebo Program to telehealth format.	X															
Add additional outcome measures to Intervention module.	X															
Finalize Procedure Manual	X															
Set up Recruitment Procedures in BHM and ATL VAMC Urology Clinics	X															
In-person training sessions for Atlanta Team	X															
Newly Enrolled		15	15	15	15	16	18	18	20	20	20					
Cumulative Enrollment		15	30	45	60	76	94	112	132	152	172					
12-month Follow-up				X	X	X	X	X	X	X	X	X	X	X	X	
Monitored Participants		15	30	45	45	46	47	48	48	48	48	48	32	16		
Collect Outcome Measures		X	X	X	X	X	X	X	X	X	X	X	X	X		
Data Entry		X	X	X	X	X	X	X	X	X	X	X	X	X		
Data analysis				X	X	X	X	X	X	X	X	X	X	X	X	
Prepare and present findings at national meeting														X	X	X
Prepare and submit manuscripts for publication														X	X	X
Implement Dissemination Plan															X	X*

**On-going into the next year under direction of investigators in the GRECC*

Based on our experience in the developmental study, it will require 1 month to get the contract with the telehealth vendor established, during which time we will do final edits to the intervention and control telehealth programs. Dr. Muta Issa, Chief of Urology at the Atlanta VAMC will review the perioperative care content. This will further assure the generalizability of the program that we developed in collaboration with Dr. Janet Colli, who was Chief of Urology at the Birmingham VAMC during the early pilot/ developmental study. We also have added Dr. Katharina Echt, who contributes expertise in aging, health literacy, training and technology usability to the study team; she will further revise the content for optimal presentation.

Once the content is finalized, the telehealth vendor will translate it into the telehealth program with branching logic. The branching logic system allows each participant to have a customized rehabilitation program according to his needs. For example, how to locate the proper muscles to exercise is a skill not well

taught in most urology practices. The telehealth curriculum will start with the method that is usually successful: Screen 1 – "Practice stopping your urine steam each time you urinate until your next session." Screen 2 – "Even if you can't completely stop your urine stream, if you can slow it down, you are using the right muscles." The next day, the telehealth program will inquire about their success in stopping the stream. If they could do it, they will be instructed in pelvic floor muscle exercise technique using the same muscles. If they couldn't stop their stream, the telehealth program will present another technique to locate the pelvic floor muscles. If that method is unsuccessful, a third technique will be tried. If all 3 techniques still result in uncertainty, a phone call from the nurse practitioner will be triggered.

It will take 2 months to edit the final screens for the active intervention telehealth program, and to edit the *attention* control program as it is converted to telehealth format.

The telehealth program monitors the participants' progress each day and the study coordinator takes appropriate action the next business day. Another example of the manner in which the curriculum is individualized is that almost 100% of men have early stress leakage (leak when they cough, sneeze, bend over, lift) following radical prostatectomy, but only about 50% of men have urge incontinence ("gotta go, gotta go").[3] The telehealth program will ask the participant if he is having leakage accompanied by urgency on the way to the bathroom and then guide him to the appropriate urgency control strategy training only if needed. An outline of the entire rehabilitation program content is in Table 3 in the Intervention Section below.

Enrollment will begin when both the treatment and control home telehealth programs have been further refined by our additional experts. A combined estimated 90 prostatectomies per year are performed at the Birmingham and Atlanta VAMCs. Based on our pilot study, 85% of Veterans approached will be eligible and agree to participate. Of our first 21 pilot study patients, 2 decided to have radiation therapy instead or their prostatectomy and 1 surgery was aborted due to positive lymph nodes. Therefore, it will take 3 years to enroll all participants, and 12 more months for final outcomes assessment. Data cleaning and entry will be ongoing. The enrollment, data collection, manuscript preparation, and dissemination schedules are in the Timeline in Table 2. Dissemination of successful clinical demonstration programs is a mission of the GRECC and dissemination of this intervention will be designed during this clinical trial, but disseminated in the following year with GRECC effort.

Participants

Participants will be recruited from among men who are scheduled to undergo radical prostatectomy for treatment of prostate cancer at the Birmingham, Philadelphia, and Atlanta VA Medical Centers. Patients who are seen in the VA Medical Centers who elect to have their surgery outside of the facility can still participate in the study. In addition to recruitment at the above VA Medical Centers and in order to reach our targeted enrollment, beginning in 2015, recruitment will also take place in the Urology Clinic at the UAB Kirklin Clinic (Birmingham), the Urology Clinic at Emory St. Joseph's Hospital (Atlanta), and at the University of Pennsylvania Urology Clinic.

Inclusion and Exclusion Criteria

Inclusion criteria:

1. Patients who are seen in the Birmingham, Philadelphia, or Atlanta VA Medical Centers or University affiliated Urology clinics who are scheduled to undergo a radical prostatectomy for treatment of prostate cancer 7-28 days after possible enrollment.

2. Ability to read English. This is essential to use the telehealth program and would exclude very few of our participants in Birmingham and Atlanta. Other language versions of the telehealth program, such as Spanish, will be developed at the dissemination phase.

3. Home internet service. If the patient does not have a computer or does not wish to use their personal computer for the study, a tablet will be loaned to them.

Exclusion criterion:

1. Self-report of significant incontinence in the 6 months prior to prostatectomy. Based on data from the Prostate Cancer Outcomes Study,[2] we would expect about 14% of potential participants to have any pre-existing incontinence, 10% with minor leakage. In our pilot study of a clinic-based intervention at the Birmingham VAMC (Preliminary studies Section - Study #5), 2 of 30 men scheduled for prostatectomy (7%) had minor incontinence prior to prostatectomy and none of them had severe incontinence. In our prior clinical trial of preoperative pelvic floor muscle training for men undergoing radical prostatectomy, we operationalized this exclusion as "no more than 2 incontinence episodes in the last 6 months, not including post-void dribbling" and will do the same for the current proposal.[4] Men who are excluded will be offered referral to the VA Continence Clinic for perioperative rehabilitation.

Sample size

Given the primary outcome is time to event, survival analyses will be used to conduct the analyses. A one-sided log rank test with an overall sample size of 156 subjects (of which 78 are randomized to standard care and 78 are randomized to Telehealth) achieves 80% power using a one-tailed 0.05 significance level to detect a difference of 0.2000 between 0.55 and 0.35 - the proportions remaining incontinent in the two groups surviving in standard care and Telehealth respectively. This effect corresponds to a hazard ratio of 1.756. These results are based on the assumption that the hazard rates are proportional. The proposed effect size is based on our earlier research.[4] Power and sample size has been calculated using the Log-Rank procedures within PASS 11.0 (Hintze, J. (2011). PASS 11. NCSS, LLC. Kaysville, Utah, USA. www.ncss.com).

In our pilot study, after randomization, 10% of Veterans decided to have radiation instead of radical prostatectomy or were found to have positive lymph nodes during surgery and their prostatectomy aborted. These men ended participation in the study because they no longer had the risk factor for incontinence. To recruit sufficient numbers of Veterans so that we obtain the full 156 subjects indicated by our power calculation above, we will plan to randomize 10% more Veterans for a total of 172. When we reach the total of 156 Veterans having had a radical prostatectomy, we will end recruitment.

Recruitment Procedures at the VAMC

The study coordinators at each site will attend all VA urology clinic sessions in which men could be scheduled for radical prostatectomy. In our pilot study, we have found that having a recruiter in clinic is essential for optimal enrollment, as busy urologists forget to call us to enroll patients. The study will be introduced to patients scheduled for radical prostatectomy by the urologist, and then the study coordinator will obtain informed consent from willing patients. Consenting participants will then complete the brief baseline assessment in clinic. Access to the telehealth program will be given to the participant after a brief training session. Our pilot study has shown that participants who were mailed a telehealth device had no trouble setting it up. The simple set-up instructions are very clear and have been performed successfully by hundreds of Veterans and their families across the U.S. If they prefer, participants can return for a separate appointment to complete baseline assessment.

Our goal will be to enroll as many participants in person as possible. However, the study coordinator will check the surgery schedule weekly, and if a patient appears on the surgery schedule for radical prostatectomy and has not been enrolled in the study, the patient will be telephoned by Urology Clinic staff and if interested, then contacted by study staff. They will be invited to come in for an enrollment visit. As a back-up, or if the patient prefers, the study can be explained by telephone, a consent form mailed to the patient, any questions answered by telephone, and the consent form signed and mailed back. Once the consent form is returned, the baseline data can be completed by telephone, and when complete data has been received, the patient will be sent his telehealth program access.

If participants are enrolled more than 28 days before their surgery date, they will not begin the program until 28 days before surgery. As in the inclusion/exclusion criteria section, if a participant cannot start the telehealth program at least 7 days before surgery, he will be excluded. He and the urologist could decide to delay his surgery so that he could participate if the participant desires. This would not affect his prostate cancer

outcome and might improve his continence outcome. Every effort will be made to enroll participants at least 14 days before their surgery.

Recruitment Procedures at the University Affiliate Urology Clinics

Birmingham site - Patients who are planning to undergo a prostatectomy at UAB will be informed of the study by their urologist at their pre-operative appointment at The Kirklin Clinic. The urologist will put a sentence in his clinic note that the patient has been informed about the study and agreed to have a study coordinator call him with more information. The urology nursing staff will email the study coordinator (secure UAB email to secure UAB email) with the names, MR numbers, and phone numbers of all patients who agree to be called. We will not be conducting any study procedures in The Kirklin Clinic. Our study coordinator will call the patient and explain the study to him. If he agrees to participate, she will conduct an informed consent discussion, answer all the patient's questions and mail the VA consent form, the VA HIPAA and the UAB HIPAA form - Authorization for Use/Disclosure of Health Information for Research form. Should the patient wish to meet in person rather than do a telephone consent, we will meet with them at the TKC Urology Clinic during an already scheduled appointment or at the BVAMC (whatever the patient prefers). If the patient has questions once he receives the consent form in the mail, he can call and have a second discussion with the study coordinator and/or arrange an in-person visit. Should the patient request an in-person visit and provide us with a signed consent form at that visit, we will transport the consent form in a locked bag from The Kirklin Clinic to the Birmingham VAMC.

Philadelphia and Atlanta sites – Recruitment at the Affiliate Urology Clinics at Philadelphia and Atlanta will be developed by the site and approved by their VA and University IRBs as appropriate with local regulations.

Stratification and Randomization

In order to assure between-group comparability, subjects will be stratified on two dimensions with possibility of impacting outcome:

1. Age (<65 years and 65 or older) – older men are more likely to have post-operative incontinence.
2. Gleason Score (<7 and 7 or greater) - named after Donald Gleason, a pathologist at the Minneapolis VAMC who developed this important tool with other colleagues in the 1960s, to classify the differentiation of the cancer cells in the prostate biopsy; the higher the score, the more anaplastic the tumor pattern, and the more likely that the tumor has spread beyond the prostate. The Gleason score serves as an indication of the likely extent of prostate cancer and serves as a surrogate for the surgical margins that will be necessary to resect the cancer, which will occur after randomization. The more extensive the resections are associated with worse continence outcomes, contingent particularly on whether one or both neurovascular bundles could be preserved. *Seven is considered the cut point for higher risk disease.*

Within each stratum, blocked randomization will be performed using a variable block size and a table of random numbers to avoid inequity in the total number of subjects assigned to each group. Stratification will be used *only* to ensure that the treatment groups are similar on severity and treatment factors, not to compare groups. Each site will have a separate randomization schedule to avoid unequal distributions between sites. Also, blocking is used not to create comparison groups but only to ensure that the groups are similar in *size*.

Intervention

This telehealth technology allows for daily guidance via a series of interactive screens. At the time of his choosing each day, the participant interacts with a 10-minute session. Informational screens are interspersed with screens that pose questions. Some questions are on understanding of a technique, some on adherence to the rehabilitation program. Depending on the participant's answers, the telehealth program's branching logic permits different paths. For example, if the participant answers that he has not yet resumed his exercises postoperatively, the next screen will inquire about the reason. Four common reasons are listed, and appropriate information and instructions are provided depending on his endorsement of a reason. Some responses, such as repeated failure to resume exercises postoperatively, a lapse in adherence to exercises preoperatively once adherence is established, failure to master a specific skill such as urgency suppression, or

a week without using the telehealth program at all will trigger an alert to the site study coordinator so that a nurse practitioner skilled in perioperative pelvic floor muscle training can call the patient to target perceived barriers. However, most common problems have been anticipated and already integrated into the telehealth program dialogues.

The Health Buddy is connected to the telehealth program via an analog telephone line ("land line") or a cellular modem and a new interactive dialogue is downloaded each night via an automatic toll-free call. For participants with cell phones, there is no additional cost, since the cellular modem is independent of the participant's cell service. The study pays an additional fee for the service as well as purchasing the cellular modems. The device can be taken anywhere in the United States, plugged into a telephone line or accessing a cellular signal, and the rehabilitation program and data collection will proceed. A green light on the Health Buddy alerts the participant that a session is waiting. For the web-based program, the participant will access the telehealth program with their own computer or tablet or a loaned tablet. The purpose of the telehealth program dialogues is to improve adherence to the rehabilitation program through regular monitoring and proactive problem solving. In addition, the participant will need to do 5 minutes of three times daily exercises and practice his bladder control skills.

The core content of telehealth-administered, evidence-based, perioperative rehabilitation program is administered daily via 5-10-minute sessions 2 weeks preoperatively and *2 months* postoperatively. If the participant has more time before surgery, he will have slightly longer to practice his exercises (within the 7-28-day window). Program content includes education, pelvic floor muscle training, progressive exercises, and bladder control techniques and is based on the programs described in *seven* randomized, controlled trials of perioperative pelvic floor muscle rehabilitation that have successfully decreased post-prostatectomy incontinence, including our own clinical trial.[4-10] The outline of the content is shown in **Table 3**. Some redundancies are built into the curriculum for reinforcement. With the branching logic, if a participant has mastered a technique, the content will not be repeated. Real-life patient stories illustrate the teaching points in many of the sessions and function to increase personal relevance of the material and thus learner engagement. Moreover, these patient stories support skill acquisition by demonstrating or modeling the everyday application of the teaching points in the lives of the participants.

Table 3 - Outline of Telehealth-Administered, Evidence-Based Perioperative Rehabilitation Program Content

Preoperative	Postoperative
*1) General Information about prostate cancer***	1) Resuming exercises and building strength and control
2) Information about post-prostatectomy incontinence, prevalence and course**	2) Leakage management – absorbent products, skin care and odor control**
3) Goals of the rehabilitation program	3) Building muscle strength
4) Locating the pelvic floor muscles and proper contraction/relaxation technique	4) Bladder control techniques – stress, urge, post-void dribbling
5) Building muscle strength and control	5) Fluid management – drinking adequate fluid and avoiding caffeine
6) Treatment adherence	6) Maintaining control once continence is attained
7) Each session ends with a Fun Fact – including examples of famous men who have done well after prostate cancer diagnosis.**	7) Each session ends with a Fun Fact – including examples of famous men who have done well after prostate cancer diagnosis.**

** Shared content with ***attention*** control program

The written content of the telehealth program will be supplemented only by an anatomy diagram for participants using a Health Buddy. The diagram will be incorporated into the web-based program. We had planned a very brief booklet, based on the book "Staying Dry: A Practical Guide to Bladder Control," authored by the Co-PI, Dr. Kathryn Burgio, et al. and published by The Johns Hopkins University Press,[22/23] which is the basis for much of the behavioral content of the telehealth program. However, we decided not to use the booklet. We wanted to see if the telehealth program would be sufficient alone, and indeed it has been. The only supplementation that our pilot participants recommended was an anatomy diagram of the pelvic floor muscles and related anatomy, which we did not supply initially, but are now using. That no participant expressed a need for written materials, which would probably surprise many academicians. However, the daily reinforcement of the behavioral program by the telehealth program is actually much more intense than the teaching patients receive in our in-clinic training, with visits once a month. Also, each daily telehealth module can be repeated as many times as the participant desires on that particular day. Most of the pilot participants liked the daily brief telehealth sessions and information "bites," and felt it was better than a self-help manual would have been.

Using telehealth to administer an evidence-based, perioperative rehabilitation program to participants undergoing prostate cancer surgery is an innovative use of this technology. The telehealth programs have proven to be a feasible and effective means of health monitoring for chronic conditions.[12-17] It has also been used in other surgical populations: post organ transplant and post coronary artery bypass surgery. Unfortunately, no research exists to evaluate these types of telehealth programs, only the more chronic care models such as diabetes and congestive heart failure.[17] Our proposed study will begin to help fill that gap in the literature.

Treatment Fidelity

Intensive protocol training will be done for the project managers at both sites as well as for the nurse interventionist. This will occur on-site for both the Atlanta and Birmingham sites, and then be supplemented by weekly VANTS calls to prevent procedure drift and discuss problems as they arise, The PI is also available any time by cell phone to answer more urgent questions. On the weekly calls, we will review results of the interventions by the study coordinators for participants who are non-adherent to conducting their daily telehealth sessions. The nurse interventionist in Birmingham will be conducting all telephone interventions for participants at all sites who are completing their telehealth session, but not meeting learning goals. A formal monthly meeting will be conducted with the PI and nurse interventionist to review all telephone support, including content and results. Because the nurse interventionist's and the PI's offices are close together in the Birmingham office of the GRECC, we also anticipate being able to discuss these calls immediately after they occur as well.

Follow-Up

After completing the daily 2-month post-operative program, participants will complete an outcome assessment once a week until 6 months after their surgery, and then again at 9 and 12 months. Weekly, this will be the ICIQ-UI short form, and every 4 weeks the EPIC-UI and the EPI, GPI, and PSQ will be added as outlined in **Table 4**. Specifics for these measures are in the following section on Outcome Measures. For the 9- and 12-month outcomes assessment, a questionnaire will be mailed with a post-paid, pre-addressed envelope only if the patient does not respond to the telehealth session. If participants in either group do not do a weekly assessment, they will be called to prompt them to complete the assessment or offered the opportunity to complete it on the telephone.

Table 4 – Data Collection Schedule						
	Pre-op Visit	1 Month After Discharge	Ongoing in the 6-Month Post-op period	At 6 Months Post-op	At 9 Months Post-op	At 12 Months Post-op
CPRS Abstraction	H & P	Hospital Record				CPRS Clinic Notes and Medication Profile
Continence History	X					
ICIQ-UI-SF [4 items]	X		WEEKLY via telehealth program	X	X	X
EPIC-UI [4 items]	X		MONTHLY via telehealth program	X	X	X
IIQ-SF, IPSS QoL question, other QoL questions [11 items]	X**		MONTHLY via telehealth program		X	X
Exercise Adherence Measure [3 items]			MONTHLY via telehealth program - *intervention group only*	X	X	X
Bladder Control Strategy Adherence [3 items]			MONTHLY via telehealth program - *intervention group only*	X	X	X
PSQ, EPI, GPI [1 item each]	**		At 2 MONTHS post-op and then MONTHLY via telehealth program	X	X	X

CPRS = Computerized Medical Record System; **EPI** = Estimated Percent Improvement; **EPIC-UI** = Expanded Prostate Cancer Index Composite Urinary Incontinence Subscale; **GPI** = Global Perception of Improvement; **H & P** = History and Physical; **ICIQ-SF** = International Consultation on Incontinence Questionnaire – Short Form; **IIQ-SF** - Incontinence Impact Questionnaire Short Form; ***IPSS QoL***- *International Prostate Symptom Score Quality of Life*; **PSQ** = Patient Satisfaction Question

**Note that the PSQ, EPI, and GPI are patient global impressions of improvement and satisfaction and cannot be collected at baseline. *Same with return to work after surgery and return to usual activities after surgery (other QoL items)*

Participants who have not achieved continence by 12 months after their surgery will be offered treatment in the GRECC Continence Clinics.

Telehealth Equipment Return

Once the participant has completed the telehealth portion of the study, the study coordinator will check for any upcoming appointments in CPRS. If they have been loaned a tablet, it is optimal to have it returned in person. If no appointments are scheduled in the near future, the participant will be provided with a box and a postage-paid, return mailing label. The participant will be responsible for packaging the tablet in the provided box and dropping it off at the nearest UPS store. If the participant does not wish to deliver the telehealth device to the nearest UPS store or there is not a store nearby, a UPS pick-up at their home will be scheduled with the participant's permission.

Outcome Measures

The International Consultation on Incontinence Questionnaire Short-Form (ICIQ-SF) is one of a series of International Consultation on Incontinence questionnaires that have been meticulously developed and tested.[24-27] The ICI questionnaires are becoming the outcome measures of choice in incontinence clinical trials internationally,[28-29] allowing comparability between studies. The ICIQ-SF is a brief (4 items), reliable (Cronbach's alpha = 0.95), questionnaire that quantifies both symptom burden and impact of incontinence and has been validated in men and women. We have piloted the ICIQ-SF and patients have found it very quick and easy to complete. The ICIQ-SF correlated well with urodynamic outcomes in men and women,[25] and 24-hour pad tests, the International Prostate Symptom Score (IPSS), and Postoperative Patient Global Impression of Improvement (PGI-I) Score in men undergoing surgical treatment for post-prostatectomy incontinence.[26]

The primary patient outcome is time to continence as measured by the ICIQ-SF. The ICIQ-SF is designed, in part, to screen for incontinence and is completely appropriate to determine if a person no longer has incontinence. We used time to continence in our previous clinical trial of preoperative training to prevent post-prostatectomy incontinence.[4] Time to continence also has face validity since it is extremely important to the patient who wants to regain continence as soon as possible after his surgery. The ICIQ-SF will be completed weekly for 6 months post-operatively via the telehealth program. Each telehealth screen related to the ICIQ-SF will be prefaced with "During the last week" to make the timeframe clear. When a participant reports no incontinence on the ICIQ-SF (an answer of "never" to "In the last week, how often did you leak urine?") for 3 weeks in a row, we will consider him continent. We successfully used the definition of no reported leakage for 3 weeks based on weekly bladder diaries in our prior study of preoperative training to prevent post-prostatectomy incontinence.[4] Although it is likely that participants who achieve this endpoint may still have occasional leakage, such as with heavy lifting or a good laugh, experience has shown that these men do not consider themselves incontinent. The total score of the ICIQ-SF will also be used to evaluate patient outcomes. The ICIQ-SF score has shown sensitivity to change with treatment in men with post-prostatectomy incontinence.[26] We will also compare continence rates at 9 and 12 months.

Secondary Outcome Measures

Expanded Prostate Cancer Index Urinary Incontinence Subscale (EPIC-UI): This measure, validated as a stand-alone assessment, consists of 4 questions from the EPIC,[30] a health-related quality of life (HRQOL) assessment tool. The EPIC was developed based on advice from an expert panel and prostate cancer survivors, expanding the 20-item University of California-Los Angeles Prostate Cancer Index (UCLA-PCI) to 50 items that quantify symptoms and bother associated with urinary, sexual, bowel, and hormonal domains. Summary and subscale scores were derived by content and factor analyses. Reliability and validity of the total and subscales were assessed by test-retest correlation, Cronbach's alpha coefficient, inter-scale correlation, and EPIC correlation with other validated instruments. Test-retest reliability and internal consistency were high for the EPIC-UI with (r = 0.87 and Cronbach's alpha = 0.89). In addition to the subscale score, the EPIC-UI question on pad use will be used as descriptive data. Although more valid measures are now recommended, pad use is an outcome that has been used in many post-prostatectomy incontinence trials and is important for comparability across trials.

Incontinence Impact Questionnaire - Short Form (IIQ-SF) This measure, validated in men with post-prostatectomy incontinence, measures the impact of incontinence on regular activities.[31] It is a condition-

specific quality of life measure that has been widely used in incontinence clinical trials. It is sensitive to pre-post changes after treatment. See **Figure 1**.

Figure 1
Incontinence Impact Questionnaire – Short Form

Has urine leakage affected your:	Not at all	Slightly	Moderately	Greatly
1. Ability to do household chores (cooking, housecleaning, laundry)?	❑	❑	❑	❑
2. Physical recreation such as walking, swimming, or other exercise?	❑	❑	❑	❑
3. Entertainment activities (movies, concerts, etc)?	❑	❑	❑	❑
4. Ability to travel by car or bus more than 30 minutes from home?	❑	❑	❑	❑
5. Participation in social activities outside your house?	❑	❑	❑	❑
6. Emotional health (nervousness, depression, etc)?	❑	❑	❑	❑
7. Feeling frustrated?	❑	❑	❑	❑

IPSS Quality of Life Question.[32] Frequently administered with the AUA Symptom Index, this validated quality of life measure has been shown to be sensitive to change after treatment in clinical trials including our own work. It is shown in **Figure 2**.

Figure 2 - IPSS Quality of Life Question: If you were to spend the rest of your life with your urinary problem the way it is now, how would you feel about that? ↑ Delighted, Pleased, Mostly satisfied, Mixed (about equally satisfied and dissatisfied), Mostly dissatisfied, Unhappy, Terrible

Other Quality of Life Questions: We have supplemented the validated questionnaires with additional quality of life questions in much of our past research.[4,18-21] These additional data points provide additional information of the impact of incontinence. We plan to ask the participants the following questions each month 1-6 months post-operatively and again at 9 & 12 months post-operatively:

- How disturbing is the urine leakage problem to you? (not at all, somewhat, or extremely disturbing)
- How much does leakage of urine restrict your activities? (not at all, some of the time, most of the time, all of the time).
- Have you been able to return to work since your surgery? (yes, no, retired or disabled)
- Have you been able to resume your usual activities since your surgery? (yes, no)

Exercise Adherence Questionnaire: We will measure adherence to exercises monthly, more frequently as the exercise routine is being established, with a brief questionnaire used in our NIH-funded incontinence research since 1989, including our trial of pelvic floor rehabilitation for post-prostatectomy incontinence,[4]

and also, the VA Rehab R&D-funded study of pelvic floor rehabilitation for overactive bladder in men.[18] The questionnaire is shown in **Figure 3**. If the participant answers "No" to "Are you doing the pelvic floor muscle exercises?" the next two questions would not appear. Instead, the participant will see screens designed to help him surmount barriers **to adherence.** Participants in the experimental group will also get monthly measures of bladder control strategy adherence – i.e., using the pelvic floor muscles to prevent stress and urge leakage.

Figure 3 - Exercise Adherence Questionnaire

Are you doing the pelvic floor muscle exercises? (Yes or No)

If yes: How many days did you do the exercises in the last week? _____

How many exercises do you do in a typical day? _____

Patient Satisfaction Question (PSQ), Estimated Percent Improvement (EPI), and Global Perception of Improvement (GPI): As in the most recent publication by the International Consultation on Incontinence conducted in 2009, the International Scientific Committee recommended that urinary incontinence clinical trials include one or more high quality, validated instruments representing the viewpoint of the patient.[33] Subjective patient assessments have been deemed so important that in one trial of pelvic floor muscle rehabilitation in the NIH Pelvic Floor Disorders Network, it was the consensus of the expert panel to use a single global patient rating of improvement as the primary outcome measure.[34,35] We propose three patient perception assessments developed by the investigators to capture patient perceptions of improvement and satisfaction (**Figure 4**).[33] The Estimated Percent Improvement (EPI) and Global Perception of Improvement (GPI) are two simple questions that allow the patient to estimate his improvement after treatment; response on one is continuous and the other categorical. The Patient Satisfaction Question, on the other hand, captures patient satisfaction with treatment on a visual analog scale from 0 to 100%. This outcome is very important since there can be different levels of satisfaction with similar degrees of improvement and vice versa.[20,21] We used these measures in our Rehab R&D-funded project, "Behavioral Treatment for Overactive Bladder in Men," (Merit Award B02-2489R, PI - Dr. Burgio).[18]

Figure 4 – Global Patient Perception Assessments

PSQ: How satisfied are you with your progress in controlling your bladder?
Completely // Somewhat // Not at All

GPI: Overall, do you feel that you are: Much better // Better // About the same // Worse // Much worse

EPI: Estimate how much better you are on a scale from: 0% (no better) to 100% (completely better).
_____%

During validation of these assessment questions, convergent validity was established by examining the relationship between each measure and reduction of incontinence episodes (based on bladder diary), change on the Incontinence Impact Questionnaire (IIQ), a validated incontinence-specific quality of life tool, and patients' desire for another treatment. Discriminant validity was tested by examining the relationship of the global ratings to five measures not expected to be related to outcome (age, race, BMI, education level, and change in perceived pain). The PSQ, EPI and GPI demonstrated acceptable convergent and discriminant validity for measuring outcomes in studies of treatment for urinary incontinence.[33] The schedule of data collection is shown in **Table 4** (above).

Qualitative Assessment

At 6 months postoperatively, after completing the core curriculum, 30 participants in the active treatment group will complete an in-person or telephone assessment of their experience using a semi-structured interview guide developed by Dr. Woodby and our research team (**Table 5**). The telephone or in-person interview will be conducted by Dr. Katharina Echt in Atlanta to evaluate any suggestions participants have and as well as gather any suggestions for changes to the telehealth program. The session is recorded, with the participant's permission. To optimize patient feedback from those who can best express their critique and

suggestions on paper, this option will be available to participants as well. Based on participant input, modifications will be made to the telehealth curriculum.

Table 5 - Semi-Structured Interview Guide

I. Technology Issues

a. If you used a Health Buddy, can you tell me about your experience with setting up the telehealth device in your home?
   i. How easy or difficult was the initial set-up?
   ii. Where did you place the telehealth device in your house?
   iii. Was this location someplace convenient to your daily routine?
   iv. Did anyone notice the telehealth device and ask questions about it? How was it answering their questions?

b. Can you tell me about how it was to use the telehealth program?
   i. What time of day did you usually do your telehealth sessions?
   ii. How convenient or challenging was it to find the time each day to do the telehealth session?
   iii. Did you usually do this alone or was someone with you when you used the telehealth program? If someone helped: How did that work for you?
   iv. If you used a Health Buddy or loaner tablet, did you experience any problems with the telehealth equipment?

II. Module Content

a. What did you think about the information you received through the telehealth program?
   i. Was the print size easy or hard to read?
   ii. Was the information easy or challenging to understand?
   iii. Did the information flow in an order that made sense or was it confusing?
   iv. Overall, did the program move at the right speed? Or was it too slow or too fast?
   v. Was the information helpful?
   vi. What in particular was most helpful?
   vii. What was the least helpful?
   viii. What did you think about the patient stories?
   ix. What did you think about the fun facts?

b. Can you tell me about what it was like for you to do the pelvic muscle exercises?
   i. How difficult was it for you to locate your pelvic muscles?
   ii. How easy or challenging is it for you to practice the exercises each day?
   iii. What reminders do you use to help you to remember to do your exercises?

III. Overall Evaluation

a. Overall, did you like the telehealth Program?
b. Did it meet the expectations you had when you signed up for the program?
c. Does it make sense to you to learn this information using the telehealth program or would you prefer learning it another way? (like in the clinic or from a booklet)

IV. Suggestions

a. What suggestions do you have for improving the telehealth Program?
b. Is there anything else you would like to share about your experience with this equipment or information that you think we ought to know that would be helpful for other patients?
c. Would you recommend this to other men who are planning to have prostatectomy surgery?

We have been successfully using this Interview Guide during the pilot study. We will continue to collect qualitative data in the RCT. A sample size of 30 will ensure that important characteristics of participants' experiences are not overlooked and that there is sufficient variation in participants' perceptions and experiences to identify most, if not all, of the relevant themes.

As shown in **Table 6**, an N of 30 reduces the probability of missing a perspective with a 10%-incidence to less than 5%. This translates into 95% confidence of identifying any qualitative insight that will contribute to our characterization of participants experiences with the intervention.[36] This data is assisting us with improvements in the telehealth program now as a result of being used in the pilot study and will be quite useful in description of the telehealth modules development and in dissemination.

Table 6. The probability of missing a population subgroup in a random sample

	Number of Respondents							
Population Incidence	**10**	**20**	**30**	**40**	**50**	**60**	**100**	**200**
=========	=======	=======	=======	=======	=======	=======	=======	=======
.50	.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
.33	.018	<.001	<.001	<.001	<.001	<.001	<.001	<.001
.25	.056	.003	<.001	<.001	<.001	<.001	<.001	<.001
.20	.107	.012	.001	<.001	<.001	<.001	<.001	<.001
.10	.349*	.122	**.042***	.015	**.005***	.002	<.001	<.001
.05	.599	.358	.215	.129	.077	.046	.006*	<.001
.01	.904	.818	.740	.669	.605	.547	.366	.134

Data Management

The telehealth programs use encrypted data with a proprietary 128-bit encryption technology that has been approved by VA security audits and is downloaded nightly from the Health Buddy to the VA Austin Automation Center or stored on the secure vendor website. Bosch also maintains a duplicate failover facility in the VA facility at Hines IL. Both databases are synced daily so the chance of data loss is extremely low. The transfer of data is via a toll-free call at no expense to the participant. If the call is interrupted, the Health Buddy recalls the center and retransmits all of the data. Data downloads to our research site will be via a shared-access VA server, other than the programmed alerts based on patients' replies to the Health Buddy dialogues, which will be transmitted the day received to prompt a call to the patient from a nurse practitioner at our center. If a participant has not completed the telehealth outcome measures for 1 week, they will be administered in-person or by telephone and barriers will be problem solved to increase adherence. All adherence and nurse practitioner time will be tracked. We will differentiate contact necessary for the participant to master the content of the rehabilitation program from contact necessary to collect study outcome measures on time. This will be important to dissemination planning.

For the data collected at the Birmingham and Atlanta VAMCs by in-person or telephone interviews and CPRS audit, the research documents will be scanned and uploaded to a SharePoint site behind a VA firewall. The paper copies will be kept in a secure and locked location in the Geriatric Research, Education, and Clinical Center (GRECC). The data will be entered into a SPSS database and stored on a secure VA server by the data manager. Information abstracted from the VA Computerized Patient Record System (CPRS) will be entered onto paper forms that will then be entered into the same SPSS database. A back-up SPSS database will be stored on a different VA server in a different location. The databases will be deidentified. The name and study number key will be stored in separate files on each of the servers. To ensure the accuracy of the data, a percentage of the data entered from paper records will be subject to dual entry with the percentage adjusted

up or down depending on the error rate detected. Manual inspection of the forms will be done to resolve differences in the dually entered data. The principal investigator and statistician will meet with the database manager to review accrual, data entry, and examine the database for outliers or data base entry errors monthly.

Data Analysis

Preliminary Analyses

Although subjects will be stratified and randomized, the equivalency of the two groups will be evaluated on selected variables that might influence treatment outcome: study site, age, nerve sparing surgery, body mass index. The chi square statistic will be used for the categorical variables and the two-sample t test for continuous variables. Normality will be carefully assessed for continuous outcomes and if the assumption is violated, non-parametric methods will be used.

Outcome Variables Analysis

Primary outcome analysis: duration of incontinence (time to achieve continence after surgery). Participants will be considered continent if they answer that they leak urine "never" on the ICIQ-SF for 3 weeks in a row. Please see Methodology section for complete explanation of this measure. Baseline time for this measure will be the day of surgery. Median time until continence and its 95% confidence interval will be calculated per group. The duration of incontinence will be examined using the Kaplan-Meier procedure, in which all protocol eligible participants are analyzed. Men who did not have a prostatectomy – either due to positive lymph nodes during surgery or because they changed their mind and selected another treatment after randomization but before surgery will not be included in the analysis. All other men randomized will be included. The duration of incontinence will be compared between the 2 groups using the log rank test. We will also compare continence rates at 9 and 12 months.

Secondary outcome analyses (severity of incontinence, impact on quality of life, and patient reported evaluations of improvement and satisfaction with treatment) will be measured by:

1. ICIQ-SF total score
2. EPIC-UI total score
3. Pad use from the EPIC-UI
4. Patient estimation of improvement measured by the GPI and EPI
5. Patient satisfaction as measured by the PSQ
6. IIQ – total and subscale scores
7. IPSS Quality of Life Question (IPSS QoL)
8. Questions on activity restriction, amount of disturbance caused by incontinence
9. Return to work or normal activities after surgery.

Our hypothesis for the secondary outcomes is that total ICIQ-SF, EPIC-UI total Score, Pad use, GPI, EPI, PSQ, IIQ, IPSS QoL, return to work or normal activity, and amount of disturbance caused by incontinence will be better in the pelvic floor muscle rehabilitation group.

Initially, descriptive analyses will be conducted to examine distributions of the frequency of symptoms and possible covariates. Extreme values will be checked for accuracy and recoded as indicated. Transformations may be employed to correct for skewness or heterogeneity as needed.

The ICIQ-SF total score and the EPIC-UI total score will be analyzed using multiple regression analysis to regress the 6 and 12-month scores on treatment group, while controlling for baseline score (first score after catheter removal post-operatively). Pad use will be dichotomized into no pad use and any pad use. Pad use will also be analyzed descriptively as no pads, 1 pad, or 2 or more pads. The chi square statistic and the t test for independent samples will be used. Both measures are necessary for comparison with earlier studies. Multiple regression will used for the GPI, EPI, and PSQ at 6 and 12 months. There is no baseline for these measures as they are the patients' evaluations of their improvement and treatment satisfaction. For the IPSS QoL question, questions on activity restriction, disturbance, and return to work or normal activity, the chi square statistic and the t test for independent samples will be used.

Qualitative Analysis

To ensure analytic rigor, the following procedures will be followed: (1) data immersion (reading/listening and re-reading/listening to the text); (2) thematic identification and articulation (discovering, naming, defining codes/variables); (3) data categorization (developing a coding scheme); (4) pattern articulation (identifying connections within and between codes; (5) data interpretation (recognizing how the patterns transcend individual experiences and reflect larger social processes). As an analytical process, content analysis involves sorting and making sense of written and narrative data. The goal is not to generalize across a population, but rather to provide understanding and explanation from the respondent's perspective.

DISSEMINATION PLAN

Before dissemination, data from the qualitative analysis of the semi-structured interviews with participants in the active treatment group as well as any themes that arose in our debriefing meetings regarding the nurse practitioner "rescue calls" will be used for final modifications to the program.

We will be using a theoretical framework to guide dissemination, the Promoting Action on Research Implementation in Health Services (PARIHS) framework.[37140] The PARIHS model is ideal for dissemination of a telehealth-administered program because it focuses on systems of care rather than individual provider or patient response to proposed change. The PARIHS framework proposes that successful implementation of evidence in practice is dependent on the inter-relationship of three key elements: the nature of the evidence, the quality of the context, and expert facilitation. For successful implementation, evidence needs to be robust, the context receptive to change, and appropriate facilitation provided. This RRD-funded grant will provide the evidence and the successful context. The investigators will be actively involved in the dissemination process to facilitate implementation.

The dissemination will be through the VA Care Coordination/Home Telehealth (CCHT) program. As per the PARIHS framework, to establish the nature of the evidence, teaching sessions via teleconference will be done for the CCHT staff to describe the burden on Veterans as a result of a diagnosis of prostate cancer, the excellent prognosis, but the resulting incontinence in men electing surgical treatment. Further, evidence of the effectiveness of perioperative pelvic floor rehabilitation and specifically that the telehealth program is effective to assist Veterans undergoing prostate cancer surgery to recover continence sooner and that it also improves their quality of life will be presented. We will include patient testimonials from our patient debriefings and qualitative analysis. We will provide similar educational sessions for Urology Clinic nurses, nurse practitioners, and physicians assistants. Their assistance will be crucial to help identify Veterans about to have prostate cancer surgery so they can participate in the preoperative rehabilitation model. CCHT teams can also monitor the surgery schedules so that any patients missed pre-operatively can be enrolled immediately after surgery.

Per the PARIHS framework, to establish the quality of the context and receptivity to this new program, input regarding any anticipated difficulties in implementation will be solicited after each teleconference so that they can be addressed.

To provide expert facilitation during implementation, we will provide telephone support as CCHTs start using this new module and continue as long as necessary. So far in the pilot study, patient telephone support beyond a phone call to encourage a few Veterans to start the program has not been necessary. If this proves to be so in the RCT, then the CCHT personnel would not need additional expertise to monitor patients enrolled in the program. The training as described above will be sufficient for them to implement the program.

Unlike many treatment protocols developed and proven effective by research teams that average 10 years to become common practice, the delivery system for this intervention has a strong existing infrastructure, the CCHT program. As mentioned earlier in the grant proposal, there has been a 30-fold growth in the CCHT program from 10,000 Veterans served in FY2006 to 300,000 in FY2010. There are 3 major reasons for this growth: 1) the CCHT program is mandated in every VA, 2) funding to each VAMC is based on the number of Veterans enrolled, so there is motivation to enroll Veterans into the program, and 3) the Veterans really like these simple home messaging devices and take pride in the improvements in their knowledge and health. This completely fits into the Health Belief Model, which is our theoretical framework for the study. The home

messaging units cue the Veterans to action, provide the information they need for an action plan, and help them achieve benefits that are clinically meaningful.

Done optimally, dissemination will take the better part of a year and will be performed as part of the GRECC mission of disseminating successful clinical dissemination projects. GRECC investigators will also revise the content of the program as necessary in the future as guided by new science and practice.

To assist in dissemination, we will also present the results of the clinical trial at the American Urological Association annual meeting and publish the manuscripts in prominent medical journals such as JAMA or the Journal of Urology, with an article describing the development of the program in the Federal Practitioner.