LCCC 1713: **Testing The Efficacy of A Couple-focused, Tailored mHealth Intervention for Symptom Self-Management Among Men with Prostate Cancer and Their Partners**

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Signature Page

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations and ICH guidelines.

Principal Investigator (PI) Name:_____Lixin Song_____

PI Signature: _____

Date:_____

Version Date: May 28,2020

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1.0 BACKGROUND AND RATIONALE

1.1 Study Synopsis

In this study, we propose to test the efficacy of a couple-focused, web-based tailored prostate cancer symptom management program (PERC) in a randomized clinical trial. We will use a two-group (**PERC versus NCI website)** randomized controlled design and collect data at baseline (T1) and 4 (T2), 8 (T3), and 12 months (T4) among 800 patients (400 patient – partner dyads)completing initial treatment for localized prostate cancer and their intimate partners.

1.2 Background

Over 180,000 new cases of prostate cancer will be diagnosed in 2016,[1] and 92% will have localized or regional disease. [2] Despite a favorable five-year relative survival at 100%,[3] men with localized prostate cancer experience serious prolonged side effects after treatment with curative intent,[4] including urinary, sexual, bowel, and hormonal symptoms; emotional distress; and general symptoms, e.g., pain, fatigue, and sleep disturbance; and change in body image, all of which impair their quality of life (QOL).[4] For men in an intimate relationship, these symptoms disrupt couples' intimacy and relationships; [5-8] the symptoms' adverse effects on their intimate partners' QOL may be greater than the effects on patients' own QOL.[9,10]

1.3 Purpose and Rationale

Despite these challenges the patients and their partners face, as well as national guidelines on cancer survivorship from the Institute of Medicine (IOM)[11] and the American Cancer Society (ACS),[4] management of negative treatment effects remains the most unaddressed supportive care need for cancer patients and their families.[12-14] Available in-person interventions are expensive to deliver and inconvenient for patients with prostate cancer and their intimate partners to attend together. Existing web-based programs often are not couple-focused, lack theory guidance, are not tailored to patient and partner needs, and are tested in studies with major methodological flaws. (Note: "partner caregivers/intimate partners" are replaced by the term "partners" sometimes in this proposal due to space limitation).

To address the unmet care needs for survivors and their partners, Dr. Song (PI) led an interdisciplinary team to develop and test the usability and feasibility of a tailored, couple-focused mHealth intervention called **Prostate Cancer Education & Resources for Couples (PERC)**. Guided by an adapted Stress and Coping theoretical framework, PERC was developed with contribution of stakeholders (patients, partners, and oncologic care providers),[15] and findings from efficacious interventions with cancer patients and partners[16,17] and empirical evidence.[4,16-19] PERC aims to improve QOL for both patients and partners by enhancing positive appraisals of illness and boosting self-efficacy, social support from multiple sources, and healthy behaviors for symptom management. PERC uses mHealth technologies to dramatically increase couples' accessibility to post-treatment supportive care whenever and wherever they feel comfortable accessing it. [15] The three main components of PERC are: (1) online educational modules to provide information and skills training, and facilitate dyadic support; (2) a moderated online Forum to facilitate professional and peer support; and (3) a Resource Toolbox to provide additional local and national resources, and easy access to useful information and tools to improve symptom management.

We tested and further refined PERC in two pilot studies. Patients and their partners were enthusiastic about and satisfied with the PERC intervention. They found the website easy to use, and it provided quality information that improved their symptom management and QOL.[15] Based on our preliminary results, we believe that the refined PERC mHealth intervention is ready for efficacy testing in a randomized clinical trial.

2.0 STUDY OBJECTIVES/AIMS AND ENDPOINTS

In this randomized controlled trial, we will examine the efficacy of a couple-focused, web-based tailored prostate cancer symptom management program (PERC). We will use a two-group (**PERC versus NCI website)** randomized controlled design and collect data at baseline (T1) and 4 (T2), 8 (T3), and 12 months (T4) among 800 patients (400 patient - partner dyads) completing initial treatment for localized prostate cancer and their intimate partners.

2.1 **Primary Objective:** Assess the efficacy of PERC for improving QOL (total score and subscale scores of the physical, social, mental, and functional domains) among patients and their intimate partners**.**

H 1: Patients and their intimate partners randomized to PERC will report a larger increase in QOL scores (as assessed by the Functional Assessment of Cancer Treatment, FACT-G) than those randomized to the control group (usual care plus the National Cancer Institute prostate cancer website, the NCI website) at 4, 8, and 12 months post-baseline

2.1.1 Our primary outcome is the total QOL score, and each of the QOL subdomains are secondary outcomes.

2.2 **Secondary Objectives:** Test the effects of PERC on symptom appraisals and coping resources.

H 2: Patients and their intimate partners randomized to PERC will report greater improvement in secondary outcomes, positive appraisals of illness and coping resources, i.e., self-efficacy in symptom management, greater social support, and use of more healthy behaviors, at follow-ups than those randomized to the control group.

2.3 **Exploratory Objective:** Explore whether patients' race/ethnicity, education, type of cancer treatment, and couples' relationship quality at baseline moderate the effects of PERC on patient and partner QOL at follow-ups.

3.0 PATIENT ELIGIBILITY

3.1 Inclusion Criteria

The eligible patients must
(1) be between 40 and 75 years old.
(2) be within 4 months after completing initial treatment for localized prostate cancer as confirmed by patient and biopsy pathology report) with curative intent, i.e., surgery or radiotherapy +/- hormonal treatment;
(3) have no previous cancer history within the past 2 years and not currently in treatment for cancer, or have a concurrent cancer (excluding non-melanomatous skin cancer);

(4) experience prostate cancer-specific and/or general symptoms;
(5) have a partner who is willing to participate.

The eligible partners must
(1) be 18 years or older
(2) be identified as the partner by the patient
(3) not have been diagnosed with cancer or receiving treatment for cancer within the past 12 months (non-melanomatous skin cancer diagnosis/treatment is diagnosis/ treatment is acceptable) so that couples can focus their efforts on managing prostate cancer.

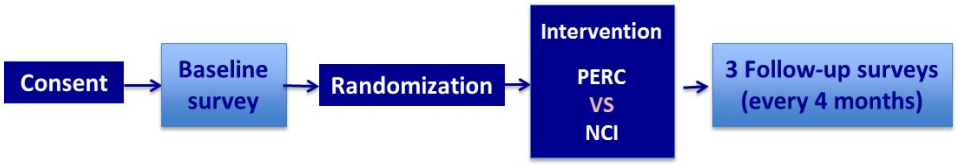
3.2 Exclusion Criteria

Patients and their partners will be excluded from the study if they:

- Do not read and speak English (evidenced by their understanding and responses to screening questions and self-reported ability to read English);
- Have cognitive impairment (assessed by the Short Portable Mental Status Questionnaire).

4.0 STUDY PLAN

4.1 Schema



4.2 Duration of Study

In this 5-year RCT, participants randomly assigned to the PERC group (the experimental group) will have access to the mHealth intervention titled Prostate Cancer Resources for Couples (PERC). The PERC users will have the chance to "meet" with a nurse educator via telephone and/or zoom video conferencing every 3-5 weeks for approximately 16-20 weeks. These will be scheduled via phone calls, emails or secure text messages (see section 4.3 below) to occur at these approximate time points: 1 week after completing the Baseline Survey (T1), and then three more at 3-5 week intervals for a total duration of 16 weeks. These intervals are flexible so that the patient/partner schedules can be accommodated and allow all 4 meetings to occur prior to the T2 survey. At the first intervention the Health Educator will describe how best to use the website and assist the couple to explore its features and different modules to manage post treatment symptoms whether emotional or physical. Participants will be encouraged to contact the Health Educator should they have questions.

Participants will also be given an option to utilize a tablet provided by the research team. If the participant does not have internet access, a Verizon jet pack (hot spot), along with user guide, will also be provided to the participant so that the surveys can be accessed. The tablet and jet pack will be returned when study participation is complete.

Content for subsequent interventions will be based on symptoms either member of the dyad is experiencing, making use of the PERC website for assistance in symptom

management. Dyads in the experimental group will have unlimited access to the PERC website after the final planned intervention.

Participants in the control group will have unlimited access to the NCI prostate cancer website. The Health Educator will have one phone meeting with them and their partners and answer any questions they have on accessing and navigating the NCI website. The control group will then receive emails and text messages approximately every 3-5 weeks until sixteen weeks to remind them to access the NCI website. As above, these intervals are flexible to allow for 3 reminders to be sent prior to the T2 Survey.

All participants will complete 3 follow-up surveys at around 4 (T2), 8 (T3), and 12 (T4) months post Baseline survey (T1)

4.3 Study Details

We plan to recruit 400 patient-partner dyads(800 participants) with diverse backgrounds through the NC Central Cancer Registry rapid case ascertainment (NC CCR RCA). The RCA uses an accelerated process to capture new cases within a week of diagnosis. After receiving a report of localized prostate cancer patients from RCA, we will contact patients' physicians by letter, giving them three weeks to request that a patient not be approached for study inclusion. In one of our studies that RCA facilitated, physicians opted out 81 out of 3400 patients (2.4%) due to patients' severe mental and physical illnesses or insufficient English proficiency. [108]

Study participation data will be provided back to the NC Central Cancer Registry rapid case ascertainment (NC CCR RCA) every six months.

After the 3 week window, we will mail study introduction, a brochure, an opt out letter and informed consent information to potential participants. Then we will call within two weeks to assess interest in participating, answer questions, and screen for eligibility. We will use the same procedure to screen partners' eligibility after eligible patients give permission for us to contact their partner. We will obtain informed consent from eligible patients and partners *via* telephone.

After consented patients and partners independently complete the baseline survey via telephone, dyads will be randomized to PERC or the control group using a 1:1 ratio. v will generate allocation sequences by computerized randomization with randomly permuted blocks of random sizes. The Co-I statistician (Dr. Xianming Tan) will generate allocation sequences by computerized randomization with randomly permuted blocks of random sizes. *Randomization will be Randomization will be stratified by type of treatment*, surgery or radiation with or without hormonal therapy. Randomization will be centrally allocated using REDCap to ensure the security of randomization lists from all study personnel. After randomization, dyads will be informed of group assignment via email, mailer and/or telephone (the communication

methods participants prefer) and study activities and invited to start either the PERC or NCI program.

Research staff (see **Data Management** for details) will be blinded to the randomization and collect all data using telephone survey at baseline (upon enrollment) and at 4, 8, and 12 months post-T1. Telephone surveys (recorded) will be scripted with simultaneous online data entry into REDCap database system, a secure database for data entry and management. It should be noted that password-protected REDCap will be maintained in a secure network environment and comply with UNC security regulations. Only designated research staff and investigators can access the REDCap database.

Participants will receive gift cards in the following amounts at the following timepoints for study activities: $20 at the completion of the T1 survey; $30 at the completion of the T2 survey; $30 at the completion of the T3 survey; $50 at the completion of the T4 survey. They will also receive a retention gift with an approximate value of $20 at around 6 months (between T2 and T3) and 10 months (between T3 and T4) after the T1 survey.

The research team will use the new Bank of America gift card system, which allows the study to acquire a gift card for each participant and then load and reload it with varying amounts for the baseline and 3 follow-up surveys. This is a UNC approved system, and no participant identifying data will be shared with any entity outside of study staff. At the discretion of the P.I. and the research staff, we may choose instead to send Amazon or WalMart gift cards, which would be purchased individually by the study. Gift cards will be sent following the completion of each study survey (T1, T2, T3 and T4); retention gifts will be sent at the appropriate time points. The Project Manager will oversee the acquisition and delivery of all gift cards.

We will use a secure online texting service to contact participants in combination with our landline telephone in our research office. We will send generic text message reminders for forthcoming surveys, giftcards, website features and use reminders, and health educator meetings. All Text Magic SMS messages will not contain any PHI and will be sent over password protected UNC Desktop computers that are located in a research office space at UNC School of Nursing that is designated to the project team.

1. Reminder: PERC Survey scheduled with <<STAFF NAME>> on <<DATE>> at <<TIME>>.
2. Thank you for participating in the PERC Study at UNC. Here is the link to your gift card! Contact us at unc_perc@unc.edu or 1-888-776-0037 if you have any problems claiming your card.
3. Reminder: Claim your gift card, it expires in 30 days
4. Reminder: Send back your gift card receipt to us soon please! Let us know if you have had any problems using your card.
5. Reminder: Log in to the website using your login information at https://perc.unc.edu/. Contact the PERC team for help logging in.
6. Reminder: Meet with the Health Educator Signup using the following link or call us directly to schedule your meeting!
7. Reminder Health Educator meeting scheduled for <<DATE>> at <<TIME>>.
8. Reminder: PERC webinar on <<Day>> at <<Time>>. Use this link to join.

9. Webinar posted to <<BLANK>> Section of the website! Check it out!
10. Check out the new Discussion Board post here! https://perc.unc.edu/topics/all
11. Time to schedule your survey! Let us know what times you are available.

4.4 Expected Risks

The risks of this study are minimal when compared to the knowledge and skills gained for the participants. The proposed study represents a potential benefit to participants for their post-treatment survivorship care. The PERC program has been designed to enhance post-treatment survivorship care by providing patients and partners a tool and specific resources to assess their needs and tailor the care program to their needs.

4.5 Removal of Patients from Protocol

Patients and their partners will become ineligible for further participation in this study if she or he is diagnosed with any type of cancer (eg breast, bowel etc) with the exception of non- melanomatous skin cancer or develops a condition that prevents them from fully participating in study activities such as scheduling and completing surveys, or phone meetings with the Nurse Educator. Participants will also be removed if they decide to withdraw from the study voluntarily.

5.0 TIME AND EVENTS TABLE

The baseline survey will take place after the participant's consent. The post-PERC survey will be about 16 weeks post baseline depending on the participant's schedule.

5.1 Time and Events Table

	Baseline (T1) PERC & Control	PERC Intervention	4, 8, and 12 months post-baseline (T2, T3, and T4) PERC & Control
Screening	X	Phone and/or Zoom contact, with Questionnaires at time points	
Informed Consent	X		
Randomization	X		
Quality of Life: Functional Assessment of Cancer Treatment (FACT-G): [176, 17*]	X		X
Personal factors: Demographics (age, race/ethnicity, income, and education)	X		
Charlson Comorbidity Index_ Brief[177,178^]	X		X
PROMIS measures of pain,[179] fatigue,[180] sleep disturbance[181,182]	X		X
PROMIS Cancer Anxiety and Depression measures [182,185]	X		X

Couple factors: Relationship quality: Dyadic Adjustment Scale—Brief[186-188]*	X		X
Holmes and Rahe Scale	X		X
Cancer-related factors: Type of treatment[#]	X		X
Prostate cancer symptoms: Prostate cancer Index Composite (EPIC) [9,189*#]	X		x
Cancer care **Financial Toxicity**: COST-FACIT	x		x
Appraisal of illness: Appraisal of Illness scales[190,191*]	X		X
Coping Resources: Lewis Cancer Self-Efficacy Scale[192]	X		X
PROMIS Informational, Emotional, instrumental[193-195] and social Support[196]	X		X
Adapted Med Diet Screening and physical activity[201,202*]	X		X
Measure of Adult Sedentary Time (MOST)	X		X
eHealth Literacy Scale (eHEALS)	X		X
Modified RESIDE Physical Activity Screener	X		X
Perceived Ease of Use and Program Satisfaction [203,204*]			
Physical activity logs (health diary)	X		X
PERC web activity (automatic tracking)			X

6.0 UNANTICIPATED PROBLEMS

6.1 Definition

As defined by UNC's IRB, unanticipated problems involving risks to study subjects or others (UPIRSO) refers to any incident, experience, or outcome that:

- Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Is related or possibly related to a subject's participation in the research; and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

We anticipate minimum risk of this study. The PERC and NCI websites provide a series of state-of-science resources that the participants can use at their convenience. We will also refer them to their treating doctors and nurse practitioners should any serious event happen.

6.2 Reporting

We will report to the UNC IRB using the IRB's web-based reporting system any unanticipated problem that occurs during the conduct of this study and that meets **at least** the first two criteria listed in 6.1.

7.0 STATISTICAL CONSIDERATIONS

7.1 Study Design

This study is a two-arm, parallel group randomized controlled trial (RCT) to test the efficacy of PERC, a theory-based, couple-focused, tailored mHealth program aimed to improve the QOL of patients with prostate cancer and their partners. After baseline measures (T1, following consent), 250 patient-partner dyads will be randomly assigned to PERC or to control (usual care plus the NCI website) groups. Participants will complete three surveys to assess the short, intermediate, and long-term effects of PERC: at 4 months post-T1 (T2), 8 months post-T1 (T3), and 12 months post-T1 (T4).

7.2 Sample Size and Power

We calculated power for comparing our primary outcome (overall QOL) in the Primary Objective using a standard approach for linear mixed models. Because we will assess outcomes for patients and partners separately, we applied a Bonferroni-corrected, two-sided alpha of 0.025 to allow for separate overall tests for patients and partners. This is because, although dyadic data will be modeled simultaneously, conclusions may differ for patients and partners. Based on our pilot test of PERC, we assumed a common standard deviation for the overall QOL scores of 15 points and a within-person correlation between repeated measurements of 0.75. Also, we allowed for losing up to 7% of participants every 4 months, for a total attrition of 20% through 12 months.

Under these assumptions (based on our preliminary studies), we report power for two scenarios, first allowing for attenuating effects, and then assuming constant effects. For the first scenario, we assumed that, on average, PERC would result in improved QOL relative to the control condition, but that these benefits might realistically be expected to decrease somewhat over time. Assuming that the mean difference between groups would be 7.5 points in overall QOL scores at 4 months (i.e., a moderate effect size of 0.5 that would represent a clinically meaningful difference immediately following the intervention) and that this would decrease by 15% every 4 months, randomizing 125 dyads per group would provide 90% power to reject the overall null hypothesis of no differences between groups across all time points. Furthermore, with this scenario, this sample size would provide 94% power for the 4-month comparison, 83% power for the 8-month comparison, and 51% power for the 12-month comparison. For the second scenario, we assumed that the intervention has a constant effect of 6.5 points at each time point (an effect size of 0.43). This sample size will provide at least 80% power for each comparison.

7.3 Data Analysis Plans

A detailed analysis plan will be developed prior to initiating the study; the following is a summary of the proposed plan. Unless otherwise specified, all analyses will include all randomized participants, in the arm to which they are randomized, regardless of the extent of intervention received (intention-to-treat).

Primary Objective: We will compare the longitudinal mean change in overall QOL between groups using analysis of covariance (ANCOVA), conducted using linear mixed models. Data for patients and partners will be fit together in the same model (accounting for within-dyad correlation), which will allow us to readily assess for differential treatment effects between patients and partners. Mixed models will allow for the inclusion of all observed data for all dyads, assuming any missing data are

missing at random. Each model will include fixed effects (separate for patient or partner) for group, month, group-by-month interactions, the baseline value of the outcome scale, baseline treatment type (surgery and radiation +/-hormonal therapy), number of baseline comorbidities, baseline couple relationship quality, baseline family disruptions, age, race/ethnicity, education, income, and number of people supported by the income. These covariates were selected because they are potentially associated with QOL. Models will include random dyad and participant nested within dyad effects to account for within-dyad and within-person correlations between longitudinal responses. For the primary comparison, separately for each participant type, we will first test for any differences between groups across all 3 time points using an appropriately specified 3 degree of freedom linear contrast. Only if this test is significant ($p \leq 0.025$), will we test for group differences at each time point.

Secondary Objectives: We will primarily use similar models to compare each of the QOL subdomains groups, and to test the Secondary outcome hypotheses. We will explore the potential mediating effects of appraisal and coping resources using a longitudinal path analysis model, which will not be the primary analysis for this aim because it requires much stronger assumptions than randomization as a basis for inference. The path model will be a cross-lagged longitudinal model with paths connecting all appraisal and coping variables from prior visits with QOL at subsequent visits, and paths to determine whether a patient's appraisal or coping might influence his partner's QOL, and vice versa. The model will include all appropriate within-dyad and longitudinal correlations. We will assess path model fit using several fit indices: the root mean square error of approximation (RMSEA), along with a 90% confidence interval, Bollen's incremental fit index (IFI), and the Tucker-Lewis fit index (TLI).

Exploratory Objectives: We will test appropriate experimental group-by-characteristic interactions using similar linear mixed models as specified for the Primary Objective. We will only explore effects within subgroups (e.g., within race and ethnicity, high school or lower vs. college or above, higher vs. lower quality relationships, or treatment type subgroups) if the corresponding interaction terms are significant at the 5% level in their respective models. We will also analyze outcome and process data to identify critical characteristics of PERC participants, e.g., differences in racial/ethnic and education, in their PERC use patterns and outcomes (e.g., Forum users vs. non-users).

7.4 Data Management/Audit

7.4.1 Data management.

A. Rapid Case Ascertainment (RCA) will maintain the patient referral database for the proposed research project on a secure network drive at the NC Central Cancer Registry. Downloaded files from the RCA project database to the researcher portal are encrypted with PGP software by RCA staff. The encrypted files are electronically transferred through SFTP to the secure integrated research system on the UNC server. The encrypted files on the UNC server is electronically retrieved through SFTP by the authorized personnel who directly works on the research project, including the project coordinator and the health educator.

B. All survey data will be collected and managed by research staff using REDCap. study ID numbers will indicate the identities of subjects, and this information will be

accessible only to the study investigators. All questionnaires will bear study ID numbers only. Research team staff will conduct all telephone survey sessions in a private workstation in a private office designated to the research team. The telephone surveys will be recorded and reviewed by the PI, research staff at the project office to ensure adherence to the study protocol as well as data completeness and accuracy. We will randomly check at least 10% of the recordings against completed data for adherence to protocol, data completeness, and accuracy.

REDCap online database will be managed by the TraCS Clinical Research Data Management Service. NC TraCS is a key initiative of the Biomedical Informatics core of the UNC-Chapel Hill CTSA. The purpose is to provide a system and associated support resources, to enable efficient and high-quality collection and management of research data that is standards-based in design, development and implementation. Standard features of electronic clinical research data management systems are available in the web-based systems provided with the service. These include interactive data entry with real-time field validation, lab data imports, audit logs to record database modifications, database integrity checks, security (in logins, permissions based on need, and encryption), reporting, forms inventory, and exports to common statistical packages for analysis. Logging tracks all data entered in REDCap so that it can be traced back to the person who entered it. No data can be changed without showing who has made the changes. This allows the study team to ensure there is security and integrity of the data collected and submitted, there are controls surrounding this aspect. REDCap also provides for principle investigator to sign off on the data, as required in FDA studies. Although users can modify data based on their permissions, they cannot delete the subject or history of that subject. Requests to delete a subject must be made to the REDCap system administrator. Our database system provides for secure web-based data entry with the data stored on servers that staff at NC TraCS maintain. The data is encrypted during transmission. The servers are located in a secure campus area with all the appropriate physical security measures in place. The web and database servers are monitored by the TraCS IT staff, patched frequently, and scanned by a third-party vendor to ensure that they are protected against known vulnerabilities. The scanning application is the standard service for the entire campus. Access is by individual user id and is restricted to the forms and/or functions that the user needs to have. The applications themselves are written using open source tools and have also been scanned by campus security office to ensure that the applications also are protected from known exploits. The data is backed up to electronic media on a daily basis. The electronic media is secured by ITS stored in a secure area separate from the servers.

C. The study website for PERC and NCI landing is hosted and maintained by the Communication for Health Applications and Interventions (CHAI) of the UNC Lineberger Comprehensive Cancer Center. The web activity data of all participants will be deidentified (using randomly assigned user IDs) and automatically tracked via a built-in feature of the study website. The de-identified web activity data from the PERC website and the NCI website landing page at CHAI will be automatically electronically transferred through SFTP to the research office at the School of Nursing on a weekly basis.

D. All administrative data (including randomization, referral data) will be centrally managed using REDCap at the PI's research office at the School of Nursing and accessed only to the study investigators and research staff. These administrative data

will be managed separately from the deidentified, password protected, encrypted and securely transferred data including surveys and web activity data. The PI and project coordinator will examine weekly the accuracy of the data files and completeness of the data.

7.4.2. Data Monitoring/Audit.

Per our consultation with the DSMB at UNC School of Medicine, although this is a randomized clinical trial, a DSMB is not needed because this study is of such low risk. With a primary outcome of change in quality of life (QOL) between the PERC intervention and the usual care plus NCI website control groups, there would not be anything significant to provide to the DSMB that might signal a reason for the DSMB to stop a study. However, we will implement a data and safety-monitoring plan to ensure the safety of participants as well as the validity and integrity of the data. The data monitoring plans are as follows:

A.Oversight for this study will be provided by the PI with input and advice from the team. An Adverse Event Monitoring Committee oversees the conduct of the study. Chaired by the Dr. Song (PI), the committee will be comprised of all of the Co-investigators: Drs. Rini, Palmer, Chen, Nielsen, Tan, Keyserling, and Northouse. Dr. Song will chair the committee, which will meet as needed to review the activities of the study including management, personnel, recruitment, performance, and any emerging problems.
The research staff will ensure all entry criteria are met prior to the initiation of the protocol and all study procedures and reporting of adverse events and unanticipated events will be performed according to the IRB-approved protocol. Any actions taken and associated follow-up activities will be recorded in the study database. All intervention-related adverse events will be reported by the PIs to the IRB within 3-7 days. The PI will submit necessary reports to NINR. The PI and the Adverse Event Monitoring Committee will assess the level of risk from adverse events as mild (no interference in usual activities); moderate (some interference in usual activities); or severe (usual activities were significantly interrupted). The PI and the Adverse Event Monitoring Committee will rate the assessment of attribution to the study as not related, unlikely, possible, probable, or definite.

B.An Independent monitor, Dr. Ray Tan (UNC Urologist), will be independent from the present study design and implementation and will be available as needed to advise oversight committees

To protect the confidentiality of participant data, the research team will conduct all research activities related to data processing involving identifiable data in a private office at the University of North Carolina-Chapel Hill School of Nursing (UNC-CH SON) that is dedicated to the project. This study has minimum hardcopy research records; the PI and the Safety Officer will ensure all records to be saved in a locked cabinet in the locked private office. With most data and documents being electronic, the PI and the Safety Officer will ensure that the identifiable and de-identified data and documents are saved separately in different project folders in the password-protected and encrypted, shared drive at the UNC-CH SON, which is on a secure UNC server. Only authorized key study personnel will have access to the identifiable information.

The de-identified electronic data will include survey recordings and the recordings of monthly meetings between the educator and study participants for

quality control, survey data, study progress data and documents, and web activity tracking data. The PI and the Safety Officer will ensure that these data are tracked using study ID with no patient identifiable information attached. As a part of the UNC network and complying with UNC security regulations, the IT staff at SON works closely with the campus IT and other technology groups to ensure both security and efficiency for the proposed study.

Adverse event reports and annual summaries will not include participant-identifiable material. Each will include the identification code only.

8.0 STUDY MANAGEMENT

8.1 Institutional Review Board (IRB) Approval and Consent

It is expected that the IRB will have the proper representation and function in accordance with federally mandated regulations. The IRB should approve the consent form and protocol.

In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to Good Clinical Practice (GCP) and to ethical principles that have their origin in the Declaration of Helsinki.

Before recruitment and enrollment onto this study, we will mail study brochure and consent information to potential participants referred by the NC Central Cancer Registry. The patient and his partner will also be given a full explanation of the study and will be given the opportunity to review the study information and the consent form via telephone. Each consent form will include all the relevant elements currently required by the UNC IRB or state regulations. Once this essential information has been provided to the patient and his partner the investigator is assured that they understand the implications of participating in the study, they will be asked to give consent to participate in the study by consenting verbally the IRB-approved consent form when potential participants interviewed and screened via telephone. All consent processes will be recorded and saved in a file separate from other deidentified study materials in password protected, encrypted shared drive on the UNC server.

8.2 Required Documentation

Before the study can be initiated at any site, the following documentation must be provided to the Clinical Protocol Office (CPO) at the University of North Carolina.

- A copy of the official IRB approval letter for the protocol and informed consent
- CVs and medical licensure for the principal investigator and any associate investigators who will be involved in the study
- A copy of the IRB-approved consent form

8.3 Registration Procedures

REDCap will be used to keep track of participants' recruitment and other project activities. We have used REDCap to manage our patient recruitment and project activities in the past We will register all enrolled participants in OnCore. We have also registered this project on CT.gov.

8.4 Adherence to the Protocol

Except for an emergency situation in which proper care for the protection, safety, and well-being of the study patient requires alternative treatment, the study shall be conducted exactly as described in the approved protocol.

8.4.1 Emergency Modifications

UNC investigators may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior UNC IRB approval.

8.4.2 Single Patient/Subject Exceptions

Any request to enroll a single subject who does not meet all the eligibility criteria of this study requires the approval of the UNC Principal Investigator and the UNC IRB.

No

8.4.3 Other Protocol Deviations/Violations

According to UNC's IRB, a protocol deviation is any unplanned variance from an IRB approved protocol that:

- Is generally noted or recognized after it occurs
- Has no substantive effect on the risks to research participants
- Has no substantive effect on the scientific integrity of the research plan or the value of the data collected
- Did not result from willful or knowing misconduct on the part of the investigator(s).

An unplanned protocol variance is considered a violation if the variance meets any of the following criteria:

- Has harmed or increased the risk of harm to one or more research participants.
- Has damaged the scientific integrity of the data collected for the study.
- Results from willful or knowing misconduct on the part of the investigator(s).
- Demonstrates serious or continuing noncompliance with federal regulations, State laws, or University policies.

If a deviation or violation occurs please follow the guidelines below:

Protocol Deviations: UNC personnel will record the deviation in OnCore® (or other appropriate database set up for the study), and report to any sponsor or data and safety monitoring committee in accordance with their policies. Deviations should be summarized and reported to the IRB at the time of continuing review.

Protocol Violations: Violations should be reported by UNC personnel within one (1) week of the investigator becoming aware of the event using the same IRB online mechanism used to report UPIRSO.

Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO:

Any events that meet the criteria for "Unanticipated Problems" as defined by UNC's IRB (see section 6.1) must be reported by the Study Coordinator using the IRB's web-based reporting system.

8.5 Amendments to the Protocol

Should amendments to the protocol be required, the amendments will be originated and documented by the Principal Investigator at UNC. It should also be noted that when an amendment to the protocol substantially alters the study design or the potential risk to the patient, a revised consent form might be required.

The written amendment, and if required the amended consent form, must be sent to UNC's IRB for approval prior to implementation.

8.6 Record Retention

Study documentation includes all Case Report Forms, data correction forms or queries, source documents, Sponsor-Investigator correspondence, monitoring logs/letters, and regulatory documents (e.g., protocol and amendments, IRB correspondence and approval, signed patient consent forms).

Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study.

Government agency regulations and directives require that all study documentation pertaining to the conduct of a clinical trial must be retained by the study investigator. In the case of a study with a drug seeking regulatory approval and marketing, these documents shall be retained for at least two years after the last approval of marketing application in an International Conference on Harmonization (ICH) region. In all other cases, study documents should be kept on file until three years after the completion and final study report of this investigational study.

8.7 Obligations of Investigators

The Principal Investigator is responsible for the conduct of the clinical trial at the site in accordance with Title 21 of the Code of Federal Regulations and/or the Declaration of Helsinki. The Principal Investigator is responsible for personally overseeing the treatment of all study patients. The Principal Investigator must assure that all study site personnel, including sub-investigators and other study staff members, adhere to the study protocol and all FDA/GCP/NCI regulations and guidelines regarding clinical trials both during and after study completion.

The Principal Investigator at each institution or site will be responsible for assuring that all the required data will be collected and entered onto the Case Report Forms. Periodically, monitoring visits will be conducted and the Principal Investigator will provide access to his/her original records to permit verification of proper entry of data. At the completion of the study, all case report forms will be reviewed by the Principal Investigator and will require his/her final signature to verify the accuracy of the data.

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