LCCC 1619: **Enhancing Survivorship Care Planning for Patients with Localized Prostate Cancer Using A Couple-focused Web-based Tailored Symptom Self-management Program**

Principal Investigator
Lixin Song, PhD
5102 Carrington Hall
919-966-3612
Email: lsong@unc.edu

Principal Co-Investigator
na

Co-Investigator(s)
Deborah Mayer, PhD
Matt Nielsen, MD, MPH
Ronald Chen, MD, MPH
Sarah Birken, PhD
Xianming Tan, PhD
Mary Dunn, NP, MSN

Biostatistician
Xianming Tan, PhD

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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:___ 07/3/2017_____

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1.0 BACKGROUND AND RATIONALE

1.1 Study Synopsis

In this study, we propose to test the feasibility of the enhanced survivorship care plan (ESCP), i.e., regular survivorship care plan (SCP) plus the web link of a couple-focused, web-based tailored prostate cancer symptom management program (PERC) and to conduct an initial benefit assessment of ESCPs, as compared to a control condition, regular SCPs plus a weblink to the publicly available National Cancer Institute (NCI) prostate cancer website (control group is denoted as SCP group for remainder of document). We will use a two-group (**SCP** and **ESCP**) randomized controlled pretest-posttest design and collect data at baseline (T1) and 4 months later (T2) among 70 patients completing initial treatment for localized prostate cancer and their partners.

1.2 Background

Cancer survivorship care planning currently involves mandated use of SCPs, documents intended in part to improve survivors' understanding of treatment-related symptoms, and ultimately, to improve patient outcomes such as quality of life (QOL).[1-3] SCP use is required by several high-profile organizations such as the Commission on Cancer (CoC) and Institute of Medicine, IOM).[1-4] However, emerging evidence from randomized clinical trials (RCTs) suggests that use of SCPs does not improve health service and patient outcomes.[5-8] The lack of effects of SCPs in these areas is most likely because the content in mandated SCPs does not take into consideration patients' information and care needs during care transition.[9-11] To enhance survivorship care planning, SCPs, as part of routine care, may create a channel for distributing interventions to patients to improve their symptom self-management and outcomes.[12,13]

Survivorship care planning for patients with prostate cancer is particularly important because of the high incidence rates of prostate cancer in men in the U.S.,[15] the frequent occurrence of side effects due to treatments with curative intent[16-23] (e.g., urinary, sexual, bowel, and hormonal symptoms, emotional distress, pain, fatigue, and sleep disturbance), and reduced QOL caused by these symptoms. Most patients are reluctant to talk with professionals or at support groups about their prostate cancer and its impact on their lives due to the sensitive nature of prostate cancer and its symptoms.[24] For patients in an intimate relationship, the effects of prostate cancer symptoms on their partners' QOL are similar or worse than the effects on their own QOL.[25,26] Management of these negative effects has been the most unaddressed supportive care need for survivors and their partners.[27-29] The IOM[3] and American Cancer Society (ACS)[30] cancer care guidelines call for programs that address treatment-related effects, promote healthy behaviors, and maintain QOL for patients and their families.

1.3 Purpose and Rationale

To address the unmet care needs of patients and their partners, Dr. Song (PI) led her interdisciplinary team to develop a couple-focused, web-based tailored prostate cancer education program (i.e., PERC)[14] based on scientific evidence and input from three groups of stakeholders: patients, partners, and oncologic care providers. The theory-driven PERC program aims to improve QOL for both patients and partners through the following content and features: **(1)** 12 online education modules that provide information and skills training. The modules aim to reduce couples' negative appraisals of symptoms and symptom bothers, increase their self-efficacy, social support, and health behaviors for symptom management, and facilitate dyadic support; **(2)** a moderated chat room that facilitates professional and peer support; and **(3)** a resource center that provides additional local and national resources for couples.[14] PERC is tailored based on participants' characteristics (e.g., presence of symptoms, type of treatment, age, physical activities, diet) and preferences for mode of delivery (e.g., use of text versus audio/video). Patients and partners may access PERC on multiple platforms, including tablets, smart phones and computers. This

access enables patients and partners to receive information they may feel uncomfortable discussing with professionals or at support groups. In the two pilot feasibility studies we conducted, prostate cancer patients and partners reported high satisfaction with PERC. They reported that PERC was simple and easy to use, and that it provided quality information that improved their symptom management and QOL.

Responding to our pilot participants' suggestion of "vigorously advertising PERC" among prostate cancer patients and their partners,[14] we proposed to use SCPs as a vehicle for consistent and timely delivery of PERC and to enhance the regular SCPs. We will use a two-group randomized controlled pre-post mixed-method design. Couples in the control group will receive the **SCP (regular SCP + NCI Prostate Cancer website link**) and couples in the intervention group will receive the **ESCP** (enhanced SCP, SCP+PERC). We will collect data at baseline (T1) and 4 months (T2).

2.0 STUDY OBJECTIVES/AIMS AND ENDPOINTS

In this proof-of-concept randomized controlled pilot trial, we will examine the feasibility of ESCP and conduct an initial benefit assessment of ESCP among prostate cancer patients transitioning from active treatment to post-treatment self-management, and their partners. We hypothesize that ESCP will improve effectiveness of regular SCPs (i.e., improve patients' and partners' QOL and reduce patient use of post-treatment care services). We expect that patients with more self-efficacy, social support, and resources from PERC's symptom self-management will use less care services. If results indicate that ESCP is feasible and beneficial, we will design and conduct a definitive RCT to examine the efficacy of ESCP to enhance supportive care planning for prostate cancer survivors and their partners.

2.1 Primary Objective

To examine the feasibility of delivering ESCPs to patients and partners (as assessed by their recruitment, enrollment, and retention rates, percentage of participants' reviewed PERC sessions that are consistent with patient-reported prostate cancer symptoms, satisfaction with the ESCP, and perceived ease of use of PERC)

2.1.1 We will use a sequential explanatory mixed-method design. The project coordinator will collect data from patients, partners, administrative notes, and built-in web activity tracking system. The self-reported data include program satisfaction and perceived ease of use.

In addition, we will conduct interviews about participants' experiences of using the programs after the follow-up (T2) surveys. A subset of twenty patient-partner dyads will be interviewed together (with telephone speaker on) and then separately (when the interviewee is alone in a closed room and feels comfortable to speak freely) to learn about their shared and discrepant perceptions about the SCP/ESCP use.

2.2 Secondary Objectives

To estimate the magnitude of benefit of ESCPs. Compared with SCP patients and partners, we hypothesize that ESCP patients and partners will report greater improvement, from T1 to T2, in QOL, self-efficacy in symptom management, social support, and health behaviors to manage symptoms. Compared with SCP partners, we hypothesize that ESCP partners will report greater improvement, from T1 to T2, in appraisals of prostate cancer symptoms. For conciseness, we list the measures for each of these five outcomes in the Summary of Measures table (Section 5.1). In addition, we hypothesize that ESCP and SCP patients will differ in the number of visits to post-treatment care services at T2.

The results obtained from our analysis of these outcomes will provide initial estimates of the magnitude and range of potential benefit of ESCP and will guide our planning for the size of a future, larger-scaled RCT that will definitively determine the benefit of ESCP for prostate cancer patients and their partners.

3.0 PATIENT ELIGIBILITY

3.1 Inclusion Criteria

The eligible patients must

- Be within 4 weeks after initial treatment with curative intent for localized prostate cancer (i.e., prostatectomy or radiotherapy +/- hormonal treatment)[83] at UNC Lineberger Comprehensive Cancer Center (LCCC)
- Not be receiving treatment currently for other cancer;
- Have a partner who is 18 years of age or older and willing to participate.[30]

The eligible partners must

- Be at least 18 years of age
- Be willing to participate

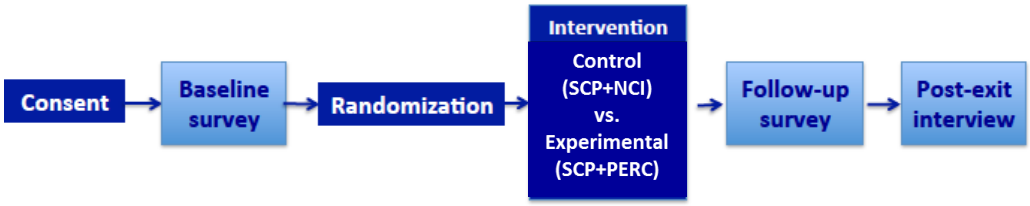
3.2 Exclusion Criteria

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

- Do not read and speak English as 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



This study will test the feasibility of a two-group randomized controlled pilot trial using pre-post mixed-method design. This pilot intervention study of 70 patients with newly diagnosed localized prostate cancer and their partners (70 couples) will examine the feasibility of ESCPs and the initial benefit of ESCPs. We anticipate that patient study participation will last at least 4 months.

Use of regular SCPs is routine, usual care at the GU clinics at UNC LCCC and Duke Cancer hospital. When a patient returns to the clinic about 2 weeks after initial treatment, his provider will complete and print a standardized SCP adapted from the American Society of Clinical Oncology (ASCO) template (see Appendix for example), review it with the patient/family in a private room behind a closed door, and provide him with a copy. The SCP will also be sent to his primary care provider via electronic health record (EHR) or fax. The SCP section about possible late- and long-term treatment effects provides a generic summary of the side effects of all types of treatment, options for managing the side effects, and recommendations for diet, physical activities, smoking cessation, and stress. All of this information is brief and presented in bullet points. One of the GU clinics is encountering a major nursing staff turnover, causing omission of SCP implementation to most patients at the clinic. While the clinic is hiring new nursing staff, an oncology nurse practitioner student who is also a staff nurse at the cancer hospital will work closely with the nurse practitioners, physician assistant, and nurse navigators to help generate and deliver the survivorship care plans with the embedded study website to eligible patients.

Participant involvement and time commitment (estimates based on our previous research)

Participant involvement	Time commitment (Minutes)
Recruitment and consent for study	
Recruitment information (introduction of study, consent information)	3-5
Recruitment, eligibility, and informed consent in-person or via telephone: patients	10
Recruitment, eligibility, and informed consent in-person or via telephone: partners of eligible patients	10
Baseline survey in person or via telephone (T1)	
For patients who are eligible	30-45
For partners who are eligible	30-45
Complete and return the receipts for the gift cards	2
The SCP review and instruction of the study website use	5-10
Moderated online Forum/meeting upon request	Variable
The SCP group: NCI website use	Variable
The ESCP group The PERC Intervention**:** Each PERC module (x 12 modules) within 14 weeks or shorter	(10-20) x 12
Follow-up telephone survey (T2): 4-month post-baseline Questionnaire	
For patients who are eligible	20-30
For partners who are eligible	20-30
Complete and return the receipts for the gift cards	2
Exit interviews	
Patient-partner jointly and separately	45-60
Complete and return the receipts for the gift cards	2
Medical record review (conducted by the project coordinator)	0

All patient participants will receive the same regular SCP with the embedded study website. Participants will log into the study website using the assigned username and passcode after being randomly assigned to either the control or experimental groups. Participants assigned to the control group will be directed to the NCI Prostate Cancer website after logging in. A web-link to NCI will be used for control participants to make the design more ecologically valid. Since in regular care, patients use a range of sources outside their doctor-nurse team and all of the regular SCP already includes a variety of resources such as American Cancer Society and MeToo. The standardized study website embedded in the SCP will ensure blinding of health care providers at the GU clinics to the study design, whereas directing control participants to NCI will also provide an equal and comparable control condition, so that we can more accurately determine the feasibility and magnitude of benefit to patients who use the PERC program with regular SCPs compared to those who receive the regular SCP and utilize the outside resources they would use normally. Patients assigned to the ESCP group will receive exactly the same SCPs as described above, but they will be directed to the PERC website after logging into the study website (see Appendix). Hence, both experimental and control groups will receive SCPs with an imbedded link that will triage based on which group they are randomized to, as the interventionist will label each participant username as belonging to either “experimental” or “control” group. The Oncology Registered Nurse research assistant will insert the web link into the regular SCP. Following routine clinical care practice, providers will review SCPs with patients during the post-treatment visit using the same procedure as they would normally. The interventionist will then provide a demonstration for patients (and partners if present) and instruct them on how to use the study websites.

4.2 Duration of Study

Participants in the ESCP group (regular SCP+PERC web link) will be able to select the intervention modules depending on the number of symptoms the patients have, and thus, the duration of participation will range between 4 weeks to 12 weeks. All participants will complete a follow-up survey at around 4 months post-baseline. See the table below for participant time commitment.

4.3 Study Details

The project coordinator will recruit patients and partners from the UNC LCCC GU and Radiation Oncology clinics, where at least 200 men with localized prostate cancer receive treatment annually (≥ 25% are African Americans), ensuring successful recruitment for this study. We will recruit couples based on procedures used successfully in the past by other researchers[73] and in our pilot study.[14] After IRB approval, the project coordinator will identify potentially eligible patients using patient scheduling systems. The project coordinator then will meet patients who meet the inclusion criteria prior to their SCP follow-up visit. The coordinator will provide study information, screen the patient and his partner for their eligibility and willingness to participate, obtain informed consent, and collect baseline data via telephone. For patients whose partners are not present at the clinic, the project coordinator will screen and consent the patients and partners via telephone after eligible patients give permission to contact their partners.

After the baseline (T1) survey, couples will be randomized to the SCP or ESCP groups using a 1:1 ratio. The study statistician (Dr. Xianming Tan) will generate the allocation sequence using a computerized randomization program with stratification by type of treatment (surgery, radiation, radiation + hormonal therapy) and randomly permuted blocks of sample sizes. We will stratify by type of treatment because it correlates with symptoms and QOL.

The interventionist will administer this allocation sequence and send couples a letter and message via email, phone or text (as they prefer) explaining their group assignment and study activities. The interventionist will then initiate ESCPs and SCP and invite couples in each group to visit the study website for log-in, following this, participants will be triaged to either PERC program or NCI website. Allocations will be concealed in sequentially numbered, opaque, sealed envelopes.

For participants in the ESCP group, participants will have 12 weeks to complete the PERC program. PERC includes 12 modules about how couples can work effectively as a team, how to assess and better manage prostate cancer treatment-related side-effects and symptoms (including urinary and bowel problems, sexual dysfunction, hormonal symptoms, pain, fatigue, sleep disturbance, and stress), and how to promote healthy behaviors. PERC also facilitates social support for the patient and his partner via post-session assignment, the moderated online chat room, and a resource center. PERC aims to help patients and their partners to improve QOL and reduce patient use of post-treatment care services by enhancing their appraisals of symptoms and self-efficacy in symptom management, facilitating social support, and promoting health behaviors.

Research staff will complete the follow-up telephone survey at 4-months post-baseline; patients and their partners will be interviewed separately. The measures for the T1 and T2 interviews include Likert-type scales of quality of life, appraisals of prostate cancer symptoms, self-efficacy in symptom management, social support, health behaviors, general symptoms, and prostate cancer symptoms, and program satisfaction and perceived ease of use. These measures demonstrated good psychometric properties in our prior studies.

For the qualitative post-intervention exit interview, all participants will be asked at the T2 survey whether they are willing to talk via telephone about their experiences of using SCPs or ESCPs. Research staff will select twenty patient-partner dyads for interviews using purposeful sampling to ensure inclusion of at

least one patient from each of the following groups: having/not having internet access, having an education level of less than high school versus higher than high school, living in rural versus urban residential locations, and being an African American versus White. We anticipate that these characteristics influence people's perceptions and use of SCPs and ESCPs, and thus, may produce differences in feasibility and design of our future study. Guided by the open-ended questions and probes on the Exit Interview Guide, patients and partners will be interviewed together (with the telephone speaker on) and then separately (when the interviewee is alone in a closed room and feels comfortable to speak freely) to learn about their shared and discrepant perceptions about the SCP/ESCP use. Research staff will conduct the qualitative interviews and collect data about the number of visits to the LCCC clinic, patients' primary care provider and other providers.

Based on the most recent research evidence on patients' willingness of using text messaging[120] we will use SMS messaging service Text Magic LTD. to deliver text message reminders to our participants concerning upcoming surveys, health educator meeting reminders, gift card reminders, gift card receipt reminders, reminders to use the study website, as well as to receive participants' inquiries and responses regarding above mentioned issues. See the SMS Messages content below. We will not send any PHI using the SMS messaging service. Text Magic does not share or sell any information including our contact list information or claim ownership over any content we send via SMS message. Text Magic will only be used in the closed office space in UNC School of Nursing using password protected UNC computers connected to secure UNC servers over UNC online network. Text Magic SMS messages will not be sent over personal devices and will only be sent in private office space using UNC desktop computers.

SMS Messages will include the following:

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 perc2017@unc.edu or 919-966-3119 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.org/. Contact the PERC team for help if needed.
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 <<topic>> on <<Day>> at <<Time>>. Use this link to join. Please send us your questions about this topic before <<date and time>>,
9. Webinar posted to <<BLANK>> Section of the website! Check it out!
10. Check out the new Discussion Board post here! https://perc-unc.org/topics/all. Feel free to join the discussion at any time to get or provide help.
11. Time to schedule your survey! Let us know what times you are available!

In addition, in order to ensure use of the intervention website and encourage use of the features of their survivorship care plans, each participant in both groups will be mailed a onetime $10 Reminder Gift along with their website log-in information, PERC project contact information, and reminder of using their SCPs with PERC or NCI during their post-treatment care experiences. The gift card and related information will be mailed in a sealed envelope to protect participant confidentiality. Participants' log-in information is not linked to any other patient identifiable information.

In addition to participant responses to structured questionnaires (70 patient-partner couples) and the audio-recorded qualitative data from the patient-partner exit interviews (a subset of 20 patient-partner couples), the research materials will also include automatically recorded web activities of the PERC program usage (participants in the ESCP group), medical record data of number of patient post-prostate cancer treatment visits to LCCC oncologic services, their primary care providers, and other providers. The administrative materials will include field notes, research activity logs, and minutes of weekly and monthly project meetings.

4.4 Expected Risks

The potential risks incurred by the study participants may include risks of emotional distress, accidental disclosure of PHI, and tension between partners. These risks, however, are minimal when compared to the knowledge and skills gained for the participants. The proposed study represents a potential benefit to participants for their survivorship care planning. ESCP uses SCPs as a vehicle of delivering the PERC program to further enhance post-treatment survivorship care planning by providing patients and partners a tool and specific resource to assess their needs and tailor the care program to their needs.

4.5 Removal of Patients from Protocol

Patients and their partners will be removed from this study if she or he is diagnosed with a new type of cancer, starts new treatment for cancer during the study period, or decides to withdraw from the study voluntarily.

5.0 TIME AND EVENTS TABLE

The baseline survey will take place after participant consent. The post-PERC survey will be about 4 months post baseline so that all participants in the ESCP group will complete the PERC intervention modules. Based on our previous experiences, the baseline and follow-up interviews will take about 30-60 minutes to complete. The post-intervention qualitative telephone exit interviews will be conducted after the participants have completed the follow-up survey. These interviews will take about 20-30 minutes. (see the Table in 4.2 for details of participant involvement and time commitment).

5.1 Time and Events Table

	Baseline (T1)	Intervention	4 months post-baseline (T2)	Post-exit interview
Screening	X	SCP vs ESCP		
Informed Consent	X			
Randomization	X			
Quality of Life	X		X	
Appraisal of prostate cancer symptoms	X		X	
Self-efficacy in symptom management	X		X	
Social support	X		X	
Health behaviors	X		X	
General symptoms	X		X	
Prostate cancer symptoms	X		X	
Comorbidities (Charlson index)	X		X	
Demographic characteristics	X			
Program satisfaction			X	
Perceived ease of use			X	
Participants' experiences of using the programs				X
Medical Records Abstraction	Continuously throughout study			

SUMMARY OF MEASURES AT BASELINE (T1) AND 4 MONTHS POST-BASELINE (T2)						
VARIABLES AND MEASUREMENT	DATA SOURCE A	GROUP	T1	T2	CRONBACH ALPHA	PERC PROGRAM[C]
Aim 1: Feasibility of ESCP						
Screening, Enrollment, and retention rates: research activity logs; field notes	AD	Both	X	X	na	na
Self-reported program use	PT, SP	Both		X	na	na
Web activity of using PERC: visit PERC or not, Number of logins, time spent on PERC, Use of modules and links	Tracking system	ESCP	X	X	na	
PERC session reviewed: # of reviewed sessions; % of reviewed sessions consistent with reported PCa symptoms	AD	ESCP		X	na	Built in tracking system in PERC
Program satisfaction and perceived ease of use: Usability Scale[82,83]	PT, SP	Both		X	na	na
Participants' experiences of using the programs: Exit Interview	PT, SP, AD	Both		X	na	na
Aim 2: Magnitude of benefits of ESCP for Survivor-Partner Couples (Compared with SCP only couples)						
MAIN OUTCOMES*: Quality of Life* (Overall, physical, emotional, and social well-being): Functional Assessment of Chronic Illness Therapy General Scale (27-item FACT-G) [82,101]	PT, SP	Both	X	X	0.90[26,82]	All
Number of visits to post-treatment care services: Medical records	HER, PT	Both		X	na	All
Appraisal of PCa symptoms: 4-item Bother Questionnaire[25,26]	SP	Both	X	X	0.74-0.9[25,26]	All
Self-efficacy in symptom management: 9-item Cancer Self-Efficacy Scale[102]	PT, SP	Both	X	X	0.91-0.96[25]	All
Social Support: Adapted supportive interaction scale[103]	PT, SP	Both	X	X	0.74-0.86[103]	PA; CR
Health behaviors: Physical Activity and Nutrition in Health Promoting Lifestyle Profile II.[104-107]*	PT, SP	Both	X	X	0.75-0.92[106,107]	HB; CR
ANTECEDENTS (CONTROL VARIABLES): PARTICIPANT CHARACTERISTICS						
Demographic Characteristics: age, race/ethnicity, income, education, and etc.	PT, SP	Both	X		na	na
Type of PCa treatment: SCP record	PT	Both	X		na	na
Comorbidities: 13-item Charlson Comorbidity Index_Brief[108,109]	PT, SP	Both	X	X	0.73-0.88[109]	na
General symptoms: 21-item Risk of Distress General Symptom Scale [110]	PT, SP	Both	X	X	0.76-0.84[22110]	GS
PCa symptoms: Prostate cancer Index Composite (EPIC) [25,111]	PT	Both	X	X	0.74-0.90[112]	PCa

Note: a: PT=patient; SP=spouse/partner; AD=Administrative data and field notes; EHR=Electronic health record; b: both=participants in SCP only and ESCP groups; c: The content elements in PERC that will impact the outcomes. PCa=prostate cancer related symptoms; GS=general symptoms of pain, fatigue, sleep disturbance, emotional distress; HB=health behaviors (Mediterranean diet and walking); PA=post-session assignment; CR=online chat room; All=all elements in PERC (mentioned above).

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 SCP and ESCP programs provide a series of resources that 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

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

7.0 STATISTICAL CONSIDERATIONS

7.1 Study Design

This is a two-group randomized controlled pretest-posttest design to test the feasibility of ESCP and estimate the magnitude of its benefits. Patients and their partners will be randomly assigned to the SCP (control) or ESCP (intervention) groups. Couples will complete baseline (T1, prior to randomization) and 4-month post-T1 follow-up measures (T2). Fifty men who recently complete initial treatment for localized prostate cancer and their partners will participate in this feasibility and proof-of-concept study.

7.2 Sample Size and Accrual

Seventy couples each will be in the SCP and ESCP groups (regular SCP+PERC intervention web link) (total N=70 couples). Conservatively, we assume that we will have complete data on 23 couples per group for our analyses, which is equivalent to assuming an attrition rate of 8%, although less attrition will result in greater statistical power. Our attrition rate is based on our previous experiences in working on the pilot study testing the feasibility of PERC in a population of patients with newly diagnosed prostate cancer and their partners recruited from UNC GU clinic (our first pilot study).

Primary Objective: Although we examine several measures to assess feasibility of ESCP, we base our calculations on the percentage of reviewed PERC sessions that are consistent with the PCa symptoms patients reported. We consider the study feasible if 80% of the reviewed PERC sessions are consistent with reported PCa reported symptoms. The built-in web activity tracking system will record and report the PERC sessions each participant reviewed; the PCa symptoms data will be collected using patient self-reported questionnaire EPIC (see the measurement summary table above) and via telephone survey. There would be 4 different types of possibilities (A, B, C, and D) between participant use of the PERC sessions and patient self-reported symptoms. The percentage of participants who reviewed the PERC sessions that are consistent with the self-reported EPIC data will be calculated as A/(A+C)

	PERC sessions reviewed	PERC sessions not reviewed
Symptom reported	A	B
Symptom not reported	C	D

It is also our belief that each of the 23 couples examined in the ESCP group will review at least one PERC session. Therefore, we will obtain a 95% confidence interval with a half width (i.e., margin of error) of at most 16% for the percentage of reviewed PERC sessions that are consistent with reported PCa symptoms. Power calculations were performed using R (version 3.2.3).

Secondary Objectives: To estimate power in testing our hypotheses of greater improvement in QOL, appraisal of prostate cancer symptoms, self-efficacy in symptom management, social support, health

behaviors from T1 to T2 among patients and partners, we use a two-sample t test with an effect size measured by Cohen's d.[114] A sample size of 23 couples per group yields 80% power to detect a moderate/large effect size of 0.74 at the one-sided 0.05 significance level. Power calculations were performed using the **pwr** package in R (version 3.2.3).

We estimate power in testing our hypothesis that ESCP and SCP patients differ in the number of visits to post-treatment care services at T2 in the context of a Poisson regression model, using a right-tailed F test. Assuming that patients in the SCP only group average 6 post-treatment care visits at T2, a sample size of 23 patients per group yields 85% power to detect an increase or decrease of 33.3% in the average number of post-treatment care visits for patients in the ESCP group (i.e., 4 or 8 post-treatment care visits at T2) at the 0.05 significance level. Power calculations were performed using SAS Version 9.4.[118]

Due to the relative newness of SCPs and the complete novelty of ESCP for prostate cancer patients, we had no prior or historical information with regards to the difference between the SCP only and ESCP groups for these main outcomes. Therefore, we computed the effect sizes used for our power calculations based on the available sample size. We recognize that these effect sizes may not be reasonable guesses of the true effect sizes as a result, but due to budgetary concerns and time constraints, we thought it best to still proceed with our calculations.

7.3 Data Analysis Plans

Primary Objective: Qualitative data will be analyzed to help explain quantitative findings.[115] First we will use a quantitative and qualitative mixed method to analyze the data.[115] We will examine research activity logs and field notes to compute enrollment, recruitment, and retention rates that will be reported by group and by time point, along with 95% confidence intervals (CI). These results will provide useful information in planning scenarios for subsequent studies. Descriptive statistics (including percentages, means, standard deviations) and their corresponding 95% CIs will also be computed for feasibility measures relating to web activity, percentage of PERC sessions reviewed that are consistent with the symptoms patients reported, as well as for self-reported use of programs and the usability scale for couples in both groups. Due to the fact that this is an exploratory proof-of-concept study, rather than a confirmatory study, we will not adjust for multiplicity when computing the CIs for these feasibility measures.

Interview data will be coded in Atlas.ti by the PI and the project coordinator using thematic analysis[116,117] based on a priori codes from our interview guide—a method we have used in a past study.[14] Members of the research team will have discussions to reconcile coding discrepancies. The responses will be analyzed based on features of PERC that are intended to make it feasible as well as participants' experiences using SCP/ESCP, to help identify the barriers and facilitators that are unique to the ESCP users. These findings will help improve PERC as well as the use of SCPs and ESCPs.

Secondary Objectives: For patients and partners in the SCP only and ESCP groups, descriptive statistics will be calculated at T1 for the measures of the following outcomes: QOL, appraisal of prostate cancer symptoms, self-efficacy in symptom management, social support, and health behaviors; at T1, descriptive statistics will be calculated for the measure of appraisal of prostate cancer symptoms for partners in both groups (see Summary of Measures table for description of the measures used for these outcomes). They will also be computed for all participant characteristics (see Summary of Measures table). At T2, descriptive statistics will also be calculated in both groups for these outcomes, the number of patient visits to post-treatment care services, and the scores for the Charlson Comorbidity Index, EPIC and the Risk of Distress General Symptom Scale. These statistics will include the mean, standard deviation, minimum, median, and maximum for each continuous variable, and frequencies and percentages for each categorical variable.

All analyses will be conducted using an intention-to-treat approach, in which all randomized participants will be analyzed according to their assigned group, regardless of the extent of intervention actually received.

For patients and partners separately, we will first use the Shapiro Wilk test to determine whether the distribution of the change score (i.e., change from T1 to T2) for the measures of each of the following main outcomes significantly differs from that a normal distribution: QOL, self-efficacy in symptom management, social support, and health behaviors. If so, we will apply a power transformation to that change score to help satisfy the assumption of normal error terms that is integral to linear models. We will then fit an analysis of covariance (ANCOVA) model to the change score for each outcome, including an indicator variable for group membership (ESCP vs. SCP only) as a predictor and the outcome's baseline (T1) measure as a covariate. In this model, we will also control for the effect of PCa treatment type (surgery, radiation, and radiation + hormonal therapy) because we stratified on PCa treatment type when we randomly assigned each couple to either the ESCP or the SCP only groups. We will also include the following participant characteristics as covariates: age, income, and the differences in the Charlson Comorbidity Index, EPIC scores, and General Symptom Scale scores between T1 and T2. We thought it appropriate to include these characteristics as covariates because they have been shown to be related to QOL and the other main outcomes. For each of these change scores, we will estimate the contrast between its model-predicted value for the ESCP group versus the SCP only group to address the hypothesis of greater improvement in QOL, self-efficacy in symptom management, social support, and health behaviors for the ESCP group.

Since the main outcome of appraisal of PCa symptoms was only measured in partners, we can only analyze it among partners. Otherwise, we will use the same approach to analyze it as we did for QOL, self-efficacy in symptom management, social support, and health behaviors.

We will fit a Poisson regression model, using a logarithm link function, to the number of patient visits to post-treatment care services at T2. In fitting this model, we will include group membership as a predictor, while controlling for the following effects: PCa treatment type (since this was our stratification variable when we randomly assigned patients to a specific group), age, income, and the Charlson Comorbidity Index, EPIC score, and the General Symptom Scale score at T2. Based on this model, we will estimate the ratio of the model-predicted number of visits to post-treatment care services at T2 for the ESCP group to that of the SCP only group to address the hypothesis that ESCP and SCP patients differ in the number of visits to post-treatment care services at T2.

To assess the effect of group on QOL, self-efficacy in symptom management, social support, and health behaviors while accounting for the fact that couples have correlated measurements, we will fit a series of linear mixed models across both patients and partners. Specifically, we will fit a linear mixed model to the change score for each measure of the outcomes of QOL, self-efficacy in symptom management, social support, and health behaviors. In doing so, we will include the following as fixed effects: group membership (ESCP vs. SCP), couple member (patient vs. partner), type of prostate cancer treatment (our stratification variable), the outcome's measure at T1, age, income, the Charlson Comorbidity Index score, and the differences in the Charlson Comorbidity Index, EPIC scores, and General Symptom Scale scores between T1 and T2. To account for the correlation among each patient and partner in a particular couple, we will also include couple membership as a random effect. Since appraisal of prostate cancer symptoms is only measured in partners and number of post-treatment care visits at T2 is only measured in patients, we cannot conduct these exploratory analyses for these two outcomes.

Since this is an exploratory proof-of-concept study, rather than a confirmatory study, we will not adjust for multiplicity when analyzing any of the previously mentioned outcomes. We expect the findings from

these analyses to be confirmed in future RCTs and that they may be used for generating hypotheses and designing new studies.

To aid in planning the sample size of a future, larger-scaled RCT, standardized effect sizes for the change scores (from T1 to T2) in the measures of QOL, self-efficacy in symptom management, social support, and health behaviors will be calculated, for patients and partners separately, as the ratio of the mean difference in each change score between the ESCP and SCP groups to its standard deviation. For partners only, we will compute this standardized effect size for the change score in appraisal of prostate cancer symptoms. For patients only, we will compute the mean number of patient visits to post-treatment care services for each group. Based on our assumption that the number of patient visits follows a Poisson distribution, this information will allow us to determine the sample size that will provide sufficient power to test the hypothesis that ESCP and SCP patients differ in the number of visits to post-treatment care services at T2.

7.4 Data Management/Audit

Per our consultation with the DSMB at UNC School of Medicine, although this is a pilot feasibility of a randomized clinical trial, a DSMB is not needed because this study is of such low risk. With one of the main outcomes as the change in QOL between the ESCP and SCP 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 and the validity and integrity of the data. The data monitoring plans are as follows.

A. The PI will convene weekly meetings with the research staff to review project progress, subject accrual, follow-up, and any anticipated and unanticipated problems. The PI will be responsible for monitoring study processes and ensuring that Adverse Events and Unanticipated Problems are reported to all relevant regulatory bodies.

B. The study consent obtained at the in-person interview at the clinic will be saved in a locked cabinet in a locked office. The consent obtained via telephone will be recorded and saved in a separate password protected and encrypted share drive at the UNC-Chapel Hill School of Nursing. The study consent will also clearly state that de-identified research data may be shared with other researchers after study completion. The research staff will explain the purpose of data sharing and the associated procedures to potential participants, as well as answer their questions related to this study.

C. Study data will be collected and stored using REDCap online database, 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 we 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.

D. Case ID numbers will indicate the identities of subjects, and this information will be accessible only to the study investigators. All questionnaires will bear case ID numbers only. For all surveys, the research staff will conduct the telephone sessions in a private research office.

E. The web activity data of participants in the SCP+PERC group will be automatically tracked via a built-in feature of the PERC website. The website for PERC is hosted and maintained by the Communication for Health Applications and Interventions (CHAI) Core of the UNC Lineberger Comprehensive Cancer Center. The de-identified web activity data from the PERC website at CHAI will be automatically, electronically transferred (thru SFTP) to the secure IRS database on a weekly basis. CHAI core also provides a secure information technology environment that is a part of the UNC network and complies with UNC security regulations. CHAI core staff engages security protocols similar to the NC TraCS as stated above.

F. A direct link to SignUp Genius will be used within the Forum section of the website to schedule meetings with the health educator during the intervention. The only information that participants will enter to sign up for meetings using SignUp Genius will be their email address, so that SignUp Genius can send them a confirmation of their time slot. The emails they enter can only be seen by the SignUp creator (i.e. health educator), so any emails that participants submit are protected from other group members. Participants will use their ID number to sign up for meetings, so that their identity remains anonymous.

G. The weekly progress information will be aggregated for reports and presented at monthly investigator meetings to determine if any of the study procedures should be altered or stopped. At these meetings, the investigators (including the project coordinator, the interventionist, 2 nurse scientists, 1 physician, 1 public health researcher, and 1 statistician) will review any adverse events, safety concerns or problems (e.g., patients' symptoms of distress), as well as assess study performance related to subject referral, recruitment and retention, protocol adherence, and the quality of the data. The investigators will assess whether the handling of issues related to participants' severe symptom distress has been appropriate and whether there is a need for improvement in the procedures. Our experienced nurse scientist consultant will also be available to discuss and provide consultation on how to ensure data and patient safety.

H. The investigators will perform continuous and close monitoring, with prompt reporting of adverse events to the IRB at UNC-CH and NIH. The investigators and staff will comply with the UNC guidelines for reporting adverse events, which require investigators to report any adverse events that are unexpected, fatal or life-threatening to the IRB using standard forms within 24 hours of the incidents. Additionally, serious adverse events and actions, if any, taken by investigators or the IRB as a result of the event or its continuing review will be reported to the NIH within 24 hours. A complete data and safety monitoring summary report will be submitted to the IRB as part of the annual renewal approval process and to the NIH with the annual progress report.

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, the patient and his partner will be given a full explanation of the study and will be given the opportunity to review the study information and the consent form. 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 signing an IRB-approved consent form when both patients and partners present at the GU clinic or by consenting verbally the IRB-approved consent form when potential participants interviewed and screened via telephone.

Prior to a patient's participation in the study, the informed consent form should be signed and personally dated in hard copy form or electronically using FDA approved DocuSign or verbally consented (and recorded) by the patient and his partner by the person who conducted the informed consent discussion.

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

A RedCap online database will be created to keep track of participants' recruitment and other project activities.

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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10.0 APPENDICES

Please include all instruments/questionnaires used in your study.