FOX CHASE CANCER CENTER
TEMPLE HEALTH

Protocol Title

Enhancing Patient-Provider Communication about Sexual Concerns in Breast Cancer

Principal Investigator

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Table of Contents

1.0 Introduction

Background: Sexual concerns are common, distressing, and persistent for many women with breast cancer yet are typically absent from care.

Objective and Hypotheses: The central goal of this research program is to develop, refine and evaluate provider and patient training programs designed to enhance communication about breast cancer-related sexual concerns. We expect that the training programs we develop and evaluate will be feasible and acceptable and that they will lead to changes in beliefs about communication related to sexuality, increases in provider-patient communication about breast cancer-related sexual concerns, and improvement in patient sexual function and QOL.

Specific Aims: (1) To develop, refine and pilot test a provider training program to enhance communication about breast cancer-related sexual concerns; (2) To develop, refine, and evaluate a patient training program to enhance communication about breast cancer-related sexual concerns.

An exploratory aim is to adapt a couple-based telephone Intimacy Enhancement intervention addressing sexual concerns for breast cancer survivors and their partners.

Study Design: First, we will identify barriers and preferences for patient-provider communication about sexual concerns and practical and preferred methods for administering the provider and patient training programs. Using qualitative interviews and focus groups with both providers and patients, we will design provider and patient training programs and refine them through expert team review and mock trainings and tailor an intimacy enhancement intervention for breast cancer survivors. Second, we will test the feasibility and acceptability of the training program in a new group of 6-8 providers, and examine change in providers' beliefs up to 6-months post-training. We expect that the frequency and quality of provider communication behaviors relating to sexuality will increase following training through coding pre- and post-training audio recorded clinic dialogue and/or through patient self-reports of communication that occurred during the clinic visits. Third, we will randomize 144 breast cancer patients with sexual concerns to a brief Skills-Based Training plus menopausal and sexual health resources or a Control condition (menopausal and sexual health resources only) prior to a routine clinic visit with a trained provider. We expect that the Skills-based training program will be feasible and acceptable and that patients will exhibit greater increases in pre- to post-training beliefs at 2-month follow-up compared with patients in the Informational Control condition. Through coding audio recorded clinic visits immediately following training, we expect that patients receiving the Skills-based training will ask more questions and express more concerns pertaining to sexuality than control patients. In additional analyses, we will examine the impact of training on psychological health, sexual function and activity, and QOL at 2-month follow-up. In a separate forthcoming study, we will pilot test the newly tailored Intimacy Enhancement intervention which will follow from the information gathered in the exploratory aim.

Significance: The lack of discussion about sexual concerns relative to the severity and importance of these concerns to women with breast cancer make this issue a major priority. The programs we develop will address an important, undertreated area of concern for breast cancer patients. Addressing breast cancer patients' sexual concerns can enhance patient-centered care and improve patients' intimate relationships and QOL.

Additionally, this study is funded by an American Cancer Society Mentored Research Scholar Grant (MRSG) to Jennifer Barsky Reese, PhD (PI) and will provide five years of funding for this research and training for the candidate to develop into an independent behavioral scientist within the cancer field. Further, R21 funding was awarded to Dr. Reese to conduct the exploratory focus groups and, in a separate study, pilot test the Intimacy Enhancement intervention developed through this aim which is being conducted in a separate study.

2.0 Objectives

2.1 Primary Objectives

2.1.1. Primary Objective I.

To develop, refine and pilot test a provider training program to enhance communication about breast cancer-related sexual concerns. First, using qualitative interviews with 12 breast cancer providers, we will design a program and then refine it through expert review and mock trainings. Through these interviews, we will identify provider barriers and preferences for communicating with patients about sexual concerns and practical and preferred methods for implementing training. Next, we will pilot test the training program in 6-8 new breast cancer providers. Outcomes will include feasibility, acceptability, and change in providers' beliefs from pre- to post-training and at 1- and 6-month follow-up. Finally, we will examine provider communication behaviors coded from pre- and post-training audio recorded clinic visits (i.e., asking questions about sexuality, offering information about sexual concerns) and/or through patient self-reports of communication that occurred during the clinic visits.

2.1.2. Primary Objective II.

To develop, and refine, and evaluate a patient training program to enhance communication about breast cancer-related menopausal and sexual concerns. First, using qualitative focus groups/interviews with 24 breast cancer survivors, we will design a Skills-based training program and will refine this program through expert review and mock trainings with 6 new breast cancer survivors. Through these focus groups, we will identify patient barriers and preferences for communicating with providers about sexual concerns and practical and preferred methods for implementing training. Next, we will randomize 144 patients to either a Skills-based training plus menopausal and sexual health resources prior to their clinic visit with a previously trained provider or a control condition (menopausal and sexual health resources only) and examine effects of the intervention on patient communication beliefs. Finally, we will examine patient communication behaviors coded from audio recorded clinic visits following the training (e.g., asking about sexual concerns, expressing a sexual concern).

2.2 Secondary Objectives

2.2.1. Secondary Objective I.

In the provider training pilot study, we will examine whether patient satisfaction (self-report) and frequency of missed opportunities for communication about sex (assessed through coding of audio recorded dialogue and/or patient self-reports of communication) change from baseline (pre-training) clinic visits to post-training clinic visits.

2.2.2. Secondary Objective II.

In the patient training study, we will examine the impact of training on psychological health and health-related QOL.

2.2.3. Secondary Objective III. As an exploratory aim, we will conduct three additional focus groups with partnered, post-treatment breast cancer survivors in which we will examine patient preference for content and structure to inform tailoring of a couple-based telephone Intimacy Enhancement (IE) intervention to the needs of breast cancer survivors. As part of the process of refining the material for the intervention study, we will also conduct a small number of cognitive interviews to review the content of the intervention material for this intervention and ensure that patients are able to read and understand the material.

2.3. Research Hypothesis

2.3.1. Hypothesis I.

We expect that the frequency and quality of provider communication about sexuality will increase following provider training.

2.3.2. Hypothesis II.
We expect that the Skills-based patient training program will be feasible and acceptable and that patients will report increased pre- to post-training beliefs and improved sexual function and other health outcomes at 2-month follow-up compared to the Control condition.

2.3.3. Hypothesis III.

We expect that patients receiving the Skills-based training will be more likely to ask a question pertaining to sexuality and raise the topic of sexuality than patients in the Control condition.

3.0 Background

3.1 Scientific Background

Advances in detection and treatment improve survival for breast cancer, yet these life-extending treatments often negatively impact sexual function and sexual quality of life (QOL).[1-3] In recent NCCN Clinical Practice Survivorship Guidelines, [4]sexual function was recognized as a critical dimension of cancer survivorship warranting assessment and intervention. Common sexual concerns for breast cancer survivors include both **physical (e.g., orgasmic difficulties, painful intercourse)**[5-7] and **motivational/emotional concerns (e.g., loss of sexual interest, body image distress)**.[8,9] For breast cancer survivors, surgical scarring can lead to perceived deformity and body image distress, hormonal therapy and chemotherapy can alter sex hormones, leading to distressing vaginal symptoms (e.g., dryness) and generalized symptoms (e.g., hot flashes),[7,10] and radiation and/or chemotherapy side effects (e.g., weight gain)[11,12] can interfere with sexuality and interest. Intimate relationships are the most fundamental relationships in many individuals' lives, and distress related to intimacy and sexual concerns can tax these relationships when this support may be most needed.[13] Sexual concerns are **distressing**[8,14] and **highly persistent for breast cancer survivors**, improving at a much slower rate than other domains of health and function.[15-18] Sexual problems correlate with poorer health outcomes including QOL and disease interference[19,20] whereas maintaining intimacy can bolster relationships and foster successful adjustment to the disease.[13,21] Addressing sexual concerns leads to improvements in mental health,[22-24] relationship quality,[24,25] and QOL in intervention studies. [23,26] Further, reducing the distressing sexual side effects of hormonal therapies can improve treatment adherence.[27] In sum, **sexual concerns are distressing**; **addressing them can have positive health effects**.

Sexual concerns are overwhelmingly neglected in cancer patients' care.[28,29] **Only 10-52% of breast cancer patients receive even basic information about sexuality**.[30-33] Most cancer patients would like more information on sexual concerns, even if treatment does not directly affect fertility or sexual performance.[34] Women with breast cancer want to preserve their sexual health and discuss these concerns with their providers.[35-37] Yet only a small subset of cancer survivors seek out psychological interventions for sexual concerns[33] and attrition is high.[38] Thus, the patient's routine clinic visit provides a potentially invaluable context for addressing these concerns, although all available data suggest that patient-provider **communication about sexual concerns is absent or of poor quality**. [28,30,34] Lack of appropriate training is overwhelmingly cited as one of the most significant barriers preventing providers from discussing sexual concerns with their patients[29,34,39,40] along with embarrassment, perceived lack of time, lack of awareness of how to respond to symptoms, and prioritizing other physical symptoms. [28,41,42] For patients, beliefs (e.g., the provider would raise the issue if important) serve as key barriers preventing them from discussing issues of sexuality with their providers. [28,30,34] For instance, although 42% of female cancer patients reported interest in receiving medical care for sexual problems in a recent study, only 7% asked for help.[37] Findings demonstrate significant barriers to communicating about sexuality for both providers and patients and suggest the importance of interventions that address both such kinds of barriers in order to improve communication about this sensitive and undertreated issue.

There is growing research demonstrating that both provider and patient communication training interventions in cancer yield positive outcomes.[43-48] Very brief interventions (<5 hours) have shown efficacy at **improving providers' knowledge, confidence, beliefs, and skills**.[49-53] These interventions are particularly effective when targeting specific provider communication behaviors such as sexual history-taking[54] and discussing prognosis with cancer patients.[55] **Importantly,**

very brief interventions have been shown to **change providers' communication behaviors related to *sexual issues***.[52] Moreover, research studies demonstrate strong support for the efficacy of very brief **patient-focused** interventions in improving patient beliefs about communication, engagement in communication with providers, and patient health outcomes.[56-59] A recent meta-analysis examining the effects of patient-focused interventions on enhancing pain control in cancer patients found that one-time interventions lasting 15-60 minutes in duration had **significant positive effects on patient beliefs, communication, and outcomes,**[56] e.g., pain. Currently, interventions such as this have not yet been tested with the aims of improving patient-provider communication and outcomes related to sexual concerns for breast cancer survivors.

In addition to the communication training proposed, empirically supported patient-focused interventions that adequately address the needs of breast cancer survivors with identified sexual concerns who want more intensive interventions suffer from limitations in both content and format. For instance, existing sexual QOL interventions do not include current management recommendations and are not generally in a format that can be widely disseminated. A telephone-based format is a viable, effective alternative to in-person counseling that would enhance the potential for dissemination and be ideal for reaching long-term survivors. Telephone-based interventions offer a viable, effective alternative to in-person psychosocial interventions that increase dissemination[60] yet few of these have been tested, and existing interventions do not incorporate important recent recommendations including strategies to promote vaginal health.[61]

3.2 Preliminary Studies

With the PROMIS Sexual Function group, we examined patients' experiences communicating with oncology providers about sex during and after treatment.[62] The **vast majority of breast cancer survivors (75%) reported that it was important to discuss sexual concerns with providers. Yet only 33% reported ever receiving information**. Few (23%) had asked about sexual concerns. Of those who had questions but did not ask, 11% cited shyness or embarrassment while 21% cited "some other reason"- indicating the need to elucidate patient barriers to raising sexual concerns. For instance, patients may not raise these issues because they are unaware that problems may develop, because they lack skills, or because of contextual factors (i.e., partnered status), though this has not been examined. We will gather such information in the proposed qualitative investigation.

We conducted an analysis of 45 audio recorded oncology visits with advanced cancer patients (67% breast cancer) from a large trial conducted by consultant and patient-provider communication expert Dr. James Tulsky, a consultant to Dr. Reese on this study. This analysis revealed *not a single mention of sexuality or intimacy*. Advanced cancer patients report sexual and intimacy-related distress[21,63] and report willingness to discuss sexuality with providers.[64] That we found not a single mention of sex or intimacy suggests that substantial efforts (i.e., both patient and provider-focused methods) are needed to increase discussion of this topic.

Previously, the PI conducted a small uncontrolled pilot study examining a telephone-based IE intervention in 14 couples facing colorectal cancer[65] and then compared the IE intervention to a wait list control in a randomized study in 23 couples (18 completed).[66] Findings showed strong positive effects on all outcomes for partners and on sexual function and self-efficacy for patients. The IE intervention holds promise for addressing the concerns of breast cancer survivors, but additional work is needed to tailor this intervention to breast cancer survivors because these populations differ in their experiences of sexual concerns, in the risk factors for worse sexual morbidity, and in appropriate management approaches. Using the qualitative data collected in the additional series of three focus groups, we will tailor this intervention to the needs of breast cancer survivors, and follow up with a separate study to finalize and evaluate this intervention.

3.3 Significance of the Research Study

Sexual concerns are common, severe, distressing, and persistent for breast cancer survivors, yet are among the most neglected topics in their care. The relative lack of discussion about sexual concerns compared to their severity and

importance make addressing this issue a major priority. The objectives of the proposed study are to develop, refine, and evaluate provider and patient training programs designed to enhance communication about breast cancer-related sexual concerns. This study has the potential for significant research and clinical impact. Ultimately, this line of research will help foster patient-centered care by integrating sexual functioning into breast cancer survivors' cancer care. This study develops and tests a novel method of improving care related to a critical and undertreated area of concern for breast cancer patients yet its effects are likely to be broader-reaching. For instance, improving communication about sexual concerns can be expected to improve patient-provider interactions and may enhance patient satisfaction with care. Intimate relationships serve as the primary source of support for individuals with cancer and buffer against the stress of managing cancer. Improving patients' sexual relationships bolsters intimate relationships, which can lead to effective coping and therefore improved mental health and overall well-being. Once developed, these interventions may also have great relevance to patients and providers of other cancers and medical conditions.

4.0 Study Design

4.1 Recruitment Methods

4.1.1 Recruitment and Reimbursement of Provider Participants

Across all three study phases, a target of 24 providers will participate in the study: 16 providers in Phase I (Qualitative Study; 8 oncologists and 4 NP's in qualitative interviews, 4 fellows for mock trainings); and 6-8 providers in Phases II (Provider Training Study) and III (Patient Training Study; approximately 6 oncologists and 2 APC's). If possible, the 6-8 providers who participate in Phase II will also be asked to participate in Phase III. To meet our recruitment goals for Phase III, we may recruit additional breast cancer clinicians for this phase. If a clinician who did not participate in Phase II agrees to participate in Phase III, he or she will be sent the Phase II provider intervention materials and asked to review them before we begin recruiting their patients for the study.

In Phase I, we anticipate enrolling 8 oncologists and 4 nurse practitioners (NPs) who treat breast cancer patients from Fox Chase/Temple affiliates or other sites to participate in qualitative interviews. If adequate qualitative information is not obtained from these interviews, additional interviews (a maximum of 6) may be held with oncologists/nurse practitioners until the data have reached "saturation" (i.e., no substantial new information is gained); alternatively, if saturation is reached with fewer provider interviews (no less than 6 oncologists and 3 NP's), we may consider stopping recruitment early for this phase. A target of four oncology fellows from FCCC (range of 3-8, depending on the adequacy of information received) will participate in the mock training. A new group of 6-8 Fox Chase/Temple or partner site breast cancer providers, consisting of oncologists and advanced practice clinicians, e.g., Nurse Practitioners, Physician Assistants, who agree to have clinic visits with enrolled patients analyzed will complete the pilot training program (Phase II). To establish a pattern of provider behavior, 8-16 patients per provider will be recruited for all phases of the clinic visit assessment study (Phases II and III; see study design figure in section 4.3), however, due to the unpredictable nature of clinic schedules, we may ultimately recruit fewer than 8 or more than 16 patients for some providers (e.g., we may recruit more heavily from some clinics if other clinics do not offer enough eligible patients)**.** We leave open a fairly wide range for the number of total audio recorded clinic visits per clinician because the total number needed will depend on the data obtained on our target outcome variables and on the number of clinicians who participate; if very few conversations occur regarding sexual concerns, we may need to record more clinic encounters. In the case that a provider participant who has consented to audio recording shares their clinic encounters with fellows, nurses, students, or another third party, those fellows will also be consented using separate consent forms so that their involvement in each clinic visit included in the study can be audio recorded.

Providers for Phase I (Qualitative Study) from Fox Chase partner sites/other sites will be recruited through provider staff meetings and through contact with FCCC providers or study team members (e.g., PI); providers may be identified with the help of the Partner Site coordinator, Kelly Filchner. Fellows for mock trainings will be recruited through routine provider meetings or contact with FCCC providers or study team members (e.g., the PI). Providers for Phases II and III

will be recruited from routine provider meetings or direct contact by the Principal Investigator (PI; Dr. Reese), who has no oversight whatsoever of the cancer providers, until enough providers have agreed to participate. An informational handout (see supplemental materials) will be sent to/emailed or given to providers describing the study; if using provider meetings to recruit, the PI will note those who are interested in the study on a separate sheet of paper along with the interested providers' contact information. Additionally, for all study phases, communication via collaborating providers on the study team will help to identify providers who are willing to discuss the study; Dr. Reese or a study team member will follow up with these providers to discuss their participation and determine eligibility. Dr. Reese or the study team member will emphasize to providers that their decision to participate is completely voluntary.

For participating in Phase I (Qualitative Study) providers will receive $75. Providers in Phase II (Provider Training) will receive $500 to compensate them for the substantial time and efforts involved in allowing us to assess communication in multiple patient visits, participate in the provider training program, and complete follow-up materials. They will receive this compensation split between three time points, in order to allow for a more timely repayment of their efforts: providers will receive $200 at the time of completion of post-intervention surveys, which will occur at the end of the provider training, another $200 once all follow-up Phase II clinic encounters have been assessed (and recorded, if possible), and a final $100 at the time of completion of the 6-month post-training survey. Fellows, nurses, students, or other third parties that are recorded as part of the clinic visit assessments will not be compensated. Providers participating in Phase III will be compensated $25 after the audio recording of their first patient and an additional $25 after the audio recording of their final patient (i.e., at the study conclusion), for a total of $50. Compensation will be provided in the form of gift cards or check.

Number of subjects per year projected at FCCC	Total target accrual	Number of subjects nationally or internationally (if applicable	Number of subjects at collaborating institutions (if applicable)
Up to: 59*	339	N/A	29*

* The yearly rate will differ by study phase. In Year 1, we anticipate enrolling up to 59 Fox Chase or Temple patient participants (though some participants may be from other outside sites) and 4 oncology fellows for Phase I; 12 Phase I providers will be recruited from Temple or other sites. In Years 2-5, we plan to enroll 256 Fox Chase patients, and 5-8 Fox Chase providers. Overall, a lower accrual goal is 305, a total target accrual goal is 339, and an upper accrual goal for Fox Chase is 349. We may also recruit Temple providers or other outside providers for Phase II if we are unable to recruit a sufficient number of internal clinicians for this phase of the study. If we are able to recruit a Temple or outside provider, then the number of target patients may change slightly for Fox Chase, because we will be recruiting about 16 patients per provider from outside Fox Chase.

4.1.2. Recruitment and Reimbursement of Patient Participants

Across all study phases, a target of 315 patients will participate in the study: 30 participants in Phase I (Qualitative Study; 24 focus group participants, 6 mock training participants); 168 patients in Phase II (Provider Training Study); and 144 in Phase III (Patient Training Study); 24 patients in the exploratory focus groups, and 5 in the cognitive interviews.

Candidates for Phase I (qualitative study/mock training) and for the exploratory focus groups will be recruited primarily through advertisements both internally via clinics at Fox Chase/Temple and externally via established community partners and other sites, telephone, and in-person at clinic at Fox Chase or Temple after identification through providers' schedules, or after identification through the Fox Chase Cancer Registry, using a study introductory letter (see supplemental materials). For patients identified through the Registry, patient lists will be approved by the patients' physician prior to sending the introductory letter. Given an approximately 20% no-show rate for the qualitative focus groups, we will recruit and schedule between 5 to 8 patients for focus groups, assuming that several candidates will not

show. Thus, the final sample size for patients may differ slightly from our estimate. Approximately twenty-four patients will participate in focus groups or interviews (three focus groups with approximately 8 patients per group) in both Phase I and the exploratory aim (for a total of approximately 48 patients over six focus groups), a new group of 6 patients will participate in the mock training sessions (range of 5-8, depending on adequacy of information received), and a new group of approximately 5 patients with the same inclusion criteria as the exploratory focus groups will participate in cognitive interviews (similar in procedure to the mock trainings; range of 4-6, depending on adequacy of information received). Larger groups present significant difficulties for recruitment and scheduling, and may be less preferable to more intimately sized groups given the sensitive topic of discussion. If adequate qualitative information is not obtained from the patient focus groups, additional focus groups may be held until the data have reached "saturation" (i.e., no substantial new information is gained; maximum of 2 focus groups per aim). Potential candidates who have not called to opt out of the study or otherwise opted out will be called or approached by a research member to confirm their eligibility. Screening will determine eligibility (see recruitment script in supplemental materials).

Candidates for Phase II (Provider Training Study) will be identified in advance through providers' schedules and will be recruited primarily in-person in the clinic or through contact with a study letter prior to their planned visit. Pre-screening by the study team will identify candidates who are eligible and the patient's provider will give final approval for approaching the patient. No separate screening is necessary. Candidates will have the opportunity to opt out either in-person, or over the telephone if contacted through the study letter in advance of their visit. For Phase III (Patient Training Study; N=144), recruitment will primarily be conducted through contact with a study letter for pre-screened patients approved by provider for contact in advance (generally 2-4 weeks) of a scheduled visit with a trained provider. Patients will have the opportunity to opt out as described above. A telephone screening call by the study team will confirm patient eligibility and assess accessibility of computer/devices, include a brief assessment of socio-demographic and medical characteristics, and health-related quality of life (e.g., level of sexual concerns, pain, fatigue), and include a detailed discussion of the study procedures. Advertisements may also be used for these phases, as needed.

For participating in Phase I (focus group/interview or mock training) or in the exploratory focus groups or cognitive interviews, participants will receive $75. Patients participating in Phase II (Provider Training Study) will receive $10 in compensation for completing the self-report materials and allowing us to assess communication during their clinic visit. For participating in Phase III, patients will receive $60 for completing the self-report materials. Compensation will be provided in the form of gift cards, which will be given to patients at the time of completion of each of the 3 assessments ($20 each; $60 total).

4.2. Inclusion and Exclusion Criteria for Provider Participants

Inclusion criteria for provider participants are presented in the following table. An exception is denoted in the table below and with an asterisk. Note that in Phase II, fellows, nurses, students, and other third parties are consenting only to have us audio record their visits, and not to participate in the provider training, and therefore we have not included information about their eligibility for provider participants below.

Inclusion Criteria for Providers
• Is an oncologist or advanced practice clinician (Nurse Practitioner, Physician Assistant) who treats breast cancer patients (Phase I qualitative interview and Phases II and II) **OR** • Is an oncology fellow who treats breast cancer patients (Phase I mock training) • Agrees to have interview audio recorded*

*Not necessary for inclusion into the Phase I (Qualitative Study) mock trainings, which will not be audio recorded

4.2.1. Inclusion and Exclusion Criteria for Patient Participants

The eligibility criteria for patient participants for all three phases of the study are presented in the table below. The slight differences in inclusion criteria for the different phases of the study are denoted.

Inclusion Criteria
• Female • Age ≥ 21 years • For Phase I: Receiving any treatment for breast cancer or have completed acute treatment for breast cancer < 5 years ago* **OR** • For Phase II or III: Receiving any treatment for breast cancer or have completed acute treatment for breast cancer < 10 years ago • Attending clinic visits in the course of follow-up care (i.e., not an initial consult visit) • Score of ≥ 3 on Patient Care Monitor Sexual Concerns screening item** • Willing to have focus group or clinic visit audio recorded, if the Phase II provider has consented to audio recording***
Exclusion Criteria
• Not able to speak English • ECOG Performance score > 2 OR too ill to participate as judged by physician, self-report, or observation of the research team member • Overt cognitive dysfunction or psychiatric disturbance or severe mental illness (e.g., dementia, suicidal behavior, or psychosis), as observed or judged by the researcher or referring source.

*Phase I mock training participants may be within 10 years of completing treatment for breast cancer

**Only necessary for inclusion into Phase I and exploratory focus groups

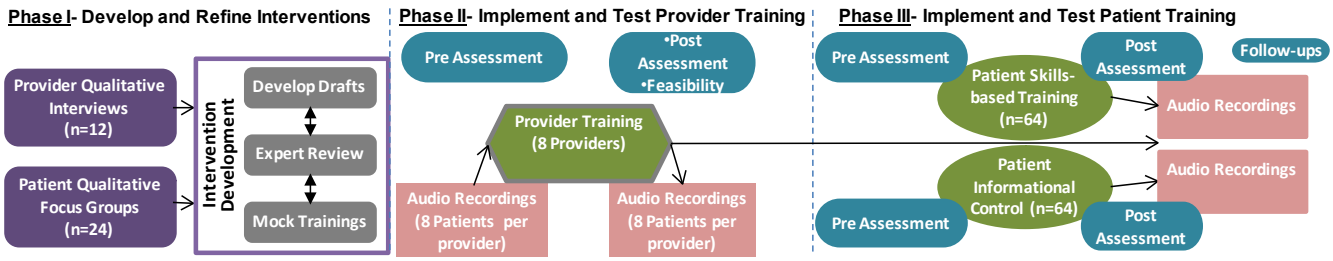
***Not necessary for inclusion into the mock trainings within Phase I (Qualitative Study) or the cognitive interviews, which will not be audio recorded

With respect to inclusion criteria for the exploratory focus groups and cognitive interviews, because post-treatment breast cancer survivors who are partnered are most severely impacted by sexual problems and are more likely to participate in an intensive couple-based intervention addressing sexual concerns, the three exploratory focus groups and cognitive interviews are designed to concentrate on this subgroup and therefore patients participating in these groups/interviews will meet the following criteria: a) has Stage I-III cancer; b) completed active treatment (e.g., chemotherapy, radiation, surgery) 6 months-5 years ago (current use of endocrine therapy is acceptable); and d) lives with a romantic partner ≥ 6 months (see recruiting script; in addition to being female, age ≥ 21 years, scoring ≥ 3 on PCM sexual concerns screening item, and being willing to have focus group audio recorded). Exclusion criteria for patients in the exploratory focus groups and cognitive interviews are as presented in the table above.

With respect to patient inclusion into Phase III, the Phase I qualitative data suggested that this intervention may be equally relevant to patients currently undergoing acute treatment (e.g., chemotherapy). Therefore, we will allow patients who are undergoing acute treatment into Phase III. Women undergoing treatment are also included in Phase II because we are interested in understanding and improving provider communication about sexual concerns across the treatment trajectory, rather than within the post-treatment phase only. For most study phases and the exploratory aim, we limit inclusion to women who are within five years of completing acute treatment because most of the research on sexual concerns in this population has been done in survivors within this timeframe and because beyond 5 years, the relationship between the breast cancer and the sexual concerns may not be well-linked. However, continuation of

endocrine therapy is acceptable for patients in all study phases because the length of use of endocrine therapy is now up to 10 years and because use of endocrine therapies is significantly linked to ongoing sexual problems. In order to allow for the broadest range of dialogue data to be collected in Phases II and III, we will allow patients into the study who are up to 10 years post-treatment. Because of the extended duration of hormonal therapy regimens to 10 years, sexual concerns are relevant to women in this group. Because discussing sexual concerns at the time of the consult visit (i.e., when many women learn of their cancer) may not be appropriate or desirable, women who are in follow-up are targeted. We limit participation in the focus groups in Phase I/exploratory aim to women reporting some degree of sexual concerns through a one-item screener given by a member of the research team (Sexual Concerns Screener on the Patient Care Monitor), in order to target these women in the development of the Skills-based intervention or the telephone-based Intimacy Enhancement intervention. We recognize that the Skills-based intervention could be relevant to women with or without sexual concerns, and thus, we would like to ensure that women from both of these groups can review the materials in our Phase I mock trainings. Because we are most interested in providers' communication in Phase II (e.g., how often they raise sexual concerns), patients in this phase are not restricted to those with sexual concerns. The Skills-based patient intervention to be tested in Phase III has content that is applicable to a wider range of patients by covering both menopausal and sexual health. For this reason, we do not plan to screen for sexual concerns for inclusion to Phase III. By including women both with and without sexual concerns in the mock trainings for this intervention, we will ensure that the intervention is appropriate and relevant to both groups of women. The patient participants in this study are limited to women because men with breast cancer are likely to have very different sexual concerns than women with breast cancer; thus, separate efforts to develop interventions targeting the sexual concerns of men with breast cancer are most likely appropriate.

4.3. Overview of Study Procedures



The study design for this research study is detailed in the figure above (numbers of patients shown in the figure are approximate) and a timeline is shown in the table below. In Phase I, we will use qualitative methods to develop and expert review and mock trainings to refine provider and patient training programs designed to enhance patient-provider communication about sexual concerns. In Phase II, we will pilot test the provider training program for feasibility and impact on provider beliefs. Through examining clinic dialogue, we will examine pre-post change in providers' communication behaviors. In Phase III, we will evaluate the feasibility and impact of the patient training on patient beliefs and sexual and QOL outcomes compared with a Control condition in a randomized trial. We will compare the two study arms on patient communication behaviors. Follow-up data will be collected at 1- and 6-months (providers) or 2-months (patients) post-training. In an exploratory aim completed alongside Phase I, we will use qualitative methods to tailor an Intimacy Enhancement intervention to address the sexual concerns of breast cancer survivors. (Exploratory focus groups are not shown in the study figure but will occur during a similar time frame as Phase I; cognitive interviews to refine the material for the Intimacy Enhancement intervention will occur during a similar time frame as the Phase I mock trainings).

Research Timeline																				
	Year 1				Year 2				Year 3				Year 4				Year 5			
Study Phase	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Study I Develop and Refine Interventions	RRC/IRB approval; Qualitative data collection/analysis; Development/ refinement of protocols; Manuscript																			
Study II Implement and Test Provider Training					BL recordings/data collection; Provider training and feasibility evaluations; Post-training recordings/data collection/analysis; Manuscript															
Study III Implement and Test Patient Training													BL data collection; Conduct patient pilot trial with post-training recordings; Analyze data; Follow-up evaluations; Manuscript/R01							

4.3.1. Qualitative Study Design (Phase I)

4.3.1.1. Provider Involvement in Qualitative Study. A very brief 6-item demographic survey will be given to providers to complete immediately after consent and before participating in the qualitative interview or mock training (see supplemental materials for self-report measures). The duration of participation for providers in this phase of the study is one visit (see section 4.4.1 for detailed information on duration of participation by study phase).

Individual qualitative interviews (45 minutes) and mock trainings will be conducted for ease of scheduling. These will generally take place at the provider's own office, for convenience. After consenting for the interview, the qualitative interviewer will begin the interview using a structured qualitative guide. The qualitative interviews will be led by Dr. Reese, who has experience conducting both qualitative interviews and focus groups or another trained member of the team. Qualitative interviews will be audio recorded so that they can be coded.

Mock training sessions will be conducted by Dr. Reese or a trained research team member and will consist of the fellow reading the program materials and responding to questions on the program content and format. Mock training sessions are expected to take 60-90 minutes, depending on the length of time it takes individual fellows to read and respond to the materials. They will also be asked to comment on the material "off the cuff" as opposed to in response to specific questions. The research team member who will be conducting the mock trainings will take notes on the comments and responses made by fellows during this session.

4.3.1.2. Patient Involvement in Qualitative Study. A very brief 15-item demographic survey will be given to patients to complete immediately after consent and before participating in the focus groups/interviews or mock training/cognitive interview (see supplemental materials). The duration of participation for patients in this phase of the study is one visit (see section 4.4.2 for detailed information on duration of participation by study phase for patients).

Overview of Study Focus Groups		
Study Phase/Aim	**Focus Group #**	**Participants**
Phase I	1	Partnered
Phase I	2	Partnered
Phase I	3	Unpartnered
Exploratory	1	Diagnosed > 45
Exploratory	2	Diagnosed > 45
Exploratory	3	Diagnosed $\leq$ 45

Six focus groups (90 minutes; see explanatory table) will be conducted in private conference rooms that can be reserved in advance, such as Conference Room B or P4031. A greater number of patients are included in Phase I focus groups relative to providers to reflect the variability in patients' experiences. To capture potentially significant differences in patient perspectives, a diverse sample will be included with respect to age, race/ethnicity, disease stage, and treatment. Within Phase I focus groups, two focus groups will be conducted with partnered patients (i.e., those who are married or in significant relationships) and one focus group will be conducted in unpartnered patients, to provide data on a range of types of sexual and intimacy concerns and because little is known about the preferences of unpartnered breast cancer patients for sexuality interventions. Additionally, in the exploratory focus groups, because younger women are at risk for worse sexual impairment[9,12] and may therefore feel more comfortable in a group with other young participants, one focus group will be limited to women diagnosed at $\leq$45 years old; the remaining two groups will include women > 45. Qualitative focus groups will be audio recorded so that they can

be coded in detail to generate qualitative themes. As mentioned previously, additional focus groups may be added if saturation has not been reached with the 3 groups per aim. Individual patient qualitative interviews may also be conducted in place of focus groups if necessary. Other than the format of the qualitative interview, the procedure will be the same (e.g., interview content/script, survey completion, same reimbursement). The PI or a trained interviewer will conduct these interviews.

Mock trainings and cognitive interviews (60-90 minutes) will include an in-depth reading of the program materials, review of materials, and feedback on format and content. Dr. Reese, and/or a trained research team member, will conduct focus groups and patient mock trainings/cognitive interviews. Mock trainings and cognitive interviews will not be audio recorded, but the research team member will take notes actively on participant responses and participants will be asked to take notes in the material as they have thoughts or comments.

4.3.2. Provider Training Study Design (Phase II)

A self-report survey will be given to providers participating in this phase to complete soon after consent (generally within one week). The table below shows the schedule of self-report measures to be completed by providers participating in the Provider Training program. At baseline (pre-training), providers will report socio-demographic information and rate self-efficacy and outcome expectancies for communicating about sexual concerns with their breast cancer patients,[67] reliable measures of beliefs associated with communication behaviors, and the extent to which they endorse certain barriers (e.g., time pressures, etc.) as limiting their communication with breast cancer patients about sexual concerns. The items assessing barriers are taken from a published study in which they showed sensitivity to change through participation in a provider training intervention.[68] Providers will complete the measures of self-efficacy and outcome expectancies at three other time points: immediately post-training, and 1- and 6-month follow-ups. Efforts will be made to collect data at all time points in person using paper and pencil questionnaires from provider participants, although telephone, web, or mail-based paper administration may also be conducted if necessary.

Provider Training (Phase II) Self-Report Measures To Be Completed by Providers				
Measure	**Baseline**	**Post-Training**	**1-Month Follow-up**	**6-Month Follow-up**
Demographics (6 items)	X	-	-	-
Beliefs [67] - Self-efficacy (3 items) - Outcome expectations (7 items) - Barriers (14 items)	X	X	X	X
Feasibility and Acceptability Items	-	X (19 items)	X (14 items)	X (14 items)
Future Program Preferences	-	-	-	X (8 items)

Patients participating in this phase of the study will complete a survey immediately after the clinic visit that includes a socio-demographic questionnaire (6 items), health-related quality of life (HRQOL) items (8 items), and several questions assessing the communication that occurred during their clinic visit, that, together, is expected to take no more than 5-10 minutes to complete. The HRQOL information captures information that will help us interpret the communication findings, while the communication items will supplement the audio recorded communication data or replace it, in cases in which we cannot obtain audio recordings of the dialogue.

Provider Training Primary Learning Targets

- **Gain familiarity** with types and causes of common sexual complaints and medical/non-medical treatments
- **Recognize** barriers to effective P-P communication
- **Learn** patients' preferred communication
- **Gain practice** and confidence in stepped care model (PLISSIT), responding to negative reactions
- **Gain awareness** of available resources/referral options
- **Learn** how to address contextual/socio-cultural factors

Between eight to sixteen clinic visits with unique patients will be assessed for communication per provider in the baseline phase of the study, resulting in at least 48 baseline visits, although we will allow a provider to participate in the training program with fewer than 8 visits recorded if it seems unlikely that we will be able to obtain this target number of visits in a timely fashion (e.g., a provider's clinic schedule has changed) approximately the same number will be assessed for communication per provider with unique patients at post-training. Sessions will be assessed until enough sessions per provider have been obtained. For each study visit that is audio recorded, two audio recording devices will be positioned in the patient examination room to catch all dialogue.

After the baseline clinic visit assessment phase is complete, as many of the Phase II providers as are willing will participate in the provider training program (see explanatory table). The goal of the provider training program is not to make providers proficient in sexual counseling. Rather, the program will focus on the first two stages of the stepped care PLISSIT model for addressing sexual concerns,[69] i.e., 1) offering permission to patients to discuss sexuality, in this case by asking about sexuality or sexual concerns, and 2) offering limited information about sexual concerns. These communication behaviors are consistent with the 2013 NCCN Clinical Practice Guidelines in Survivorship for addressing cancer survivors' sexual function[4,70] by targeting the identification of patients' sexual concerns.

Training is planned to consist of two complementary components: an educational component (e.g., informational workbook with supplemental clips or slides) and a 30-60-minute (approximate) in-person workshop, conducted in groups or pairs that will include review of material on communication about sexual concerns, viewing slides and/or videos with sample patient-clinician exchanges, and engaging in skills practice, which could consist of role-plays, discussions or drill-type exercises, , and feedback, valuable techniques in communication skills development (see Table above).[71-73]If scheduling small groups or pairs appears prohibitive, alternative approaches will be explored including individual training sessions, and two sessions may be planned if it appears difficult to cover all the material in one session. The training program will also aim to increase provider awareness of resources for in-depth information (e.g., supplying providers with pamphlets, pocket information cards, etc.)[74] and further assessment through referral to the Fox Chase Sexual Health and Menopause Clinic or elsewhere. The small group sessions will be audio recorded to facilitate post-training feasibility analyses. Following training, providers may receive periodic (e.g., weekly) emails designed to reinforce content and skills containing reminders about skills, communication tips, communication video clips, new research about sexuality in breast cancer, or quotations from interactions illustrating good/poor communication.

4.3.3. Patient Training Study Design (Phase III)

Immediately after consent, patients will be administered a baseline self-report survey. The table on the following page shows the anticipated schedule of self-report measures to be completed by patients participating in the Patient Training Study (Phase III) as well as the number of items and estimated length of time needed to complete the survey at both time points. Assessments will primarily be conducted using RedCap forms, which are HIPAA compliant and convenient for participants, particularly for baseline (T1) and 2-month follow-up data (T3), whereas post-intervention (T2) data will generally be collected primarily in-person in clinic immediately following the clinic visit which was audio recorded. However, survey data may be administered using paper-based forms in the case that patients are unable or unwilling to complete online surveys and can be collected either through the mail or in person; telephone collection may also be used if needed to facilitate efficient and timely gathering of follow-up data. Medical data will be collected from medical records and include: stage of disease, dates of diagnosis, surgeries, and treatments, and current and past breast cancer treatments.

We will use block randomization to randomize patients 1:1 to either condition with stratification by (a) metastatic disease (Stage IV) vs. non-metastatic disease (anything other than Stage IV) and (b) education (less than or equal to 12 years of education, i.e., a high school diploma) vs. any more than a high school education (equivalent to more than 12 years of education) to assign 64 patients to the Skills-based training plus menopausal and sexual health resources and 64 patients to the Control condition (menopausal and sexual health resources only).

The patient training intervention will consist of multiple aspects such as PowerPoint slides with voiceover and audio or video clips, along with a workbook. The materials will be sent to participants using a RedCap link, after consent, completion of baseline surveys, and randomization. Patients will be able to complete the intervention either at home using their own computer or other device, or in-person in a private location at Fox Chase, either in advance of their clinic visit or the day of their clinic visit. This flexibility will allow patients without computer access to participate, while still maintaining a consistent time frame in which the assessments and intervention will be delivered.

Patient Training Study (Phase III) Patient Self-Report Measures					
Measure	**# Items**	**Minutes to Complete**	**Baseline**	**Post-Training**	**2-Month Follow-up**
Demographics	7	5	X	-	-
Patient-Provider Communication Self-Efficacy (PEPPI-5)	5	3	X	X	X
Beliefs (Self-efficacy/Outcome expectations)[67,75]	18	5	X	X	X
Barriers to discussing sexual health	13	4	X	-	X
Self-Report of Communication During Patient Visit	20	10	-	X	-
Hospital Anxiety and Depression Scale (HADS)	27	10	X	-	X
Dyadic Adjustment (DAS-4) [76]	4	2	X	-	X
Quality of Life (FACT-B Brief) [77]	23	10	X	-	X
HRQOL Items	10	4	-	X	-
PROMIS SexFS Brief Profile Version 2 (Female)[78]	14	5	X	-	X
Information/Help-Seeking [79]	3	2	X	-	X
Therapeutic Aids [80]	3	3	X	-	X
Satisfaction with Interaction with Provider [81]	4	2	-	X	-
Program Evaluation (Skills-Based Training patients only)	20	10	-	X	-
Resources Evaluation	6	3	-	X	-
Totals - Baseline (T1) - Post-Training (T2) - 2-Month Follow-up (T3)	 117 77 126	 49 37 44			

Skills-Based Training. Details of this intervention have been informed by the results from both Phases I and II. Using a social cognitive framework,[82] the 20-minute intervention (Starting the Conversation) consists of an informational and skills-based video and accompanying workbook. This intervention is designed to increase self-efficacy and outcome expectancies for communicating with providers about menopausal and sexual health, reduce barriers to communication, and provide basic training in skills for communicating with providers about menopausal and sexual health, including prioritizing concerns, tips for effective communication, communication practice, and self-feedback. Planned communication content and structure are influenced by other skills-based patient-focused training interventions in cancer[57,83], results from Phases I and II of our study (e.g., patient cognitive interviews, data from clinic dialogue

suggesting that patients infrequently ask questions during clinic visits), current research on menopausal and sexual side effects of breast cancer treatment, and the input of study team members who have expertise in patient-provider communication (Beach), behavioral patient interventions (Reese, Lepore, Porter), breast cancer (Daly), and menopausal and sexual health for women with cancer (Reese, Schwartz). In addition to viewing the module, participants will be sent a workbook to go along with the video module. Patients in the Skills-Based Training condition will also receive resources on menopausal and sexual health for breast cancer survivors, in the form of a list of informational resources (e.g., websites, Fox Chase resources or clinics). Control Condition. Patients randomized to the Control group will receive the same list of menopausal and sexual health resource guide as the patients in the Skills-Based Training group, but will not be asked to participate in the Starting the Conversation intervention. After completion of all study measures and the recording of their clinic visit, interested Control group patients will be offered the opportunity to participate in Starting the Conversation (i.e., to watch the video and use the workbook).

The patient's first clinic appointment following her participation in the patient training program with the post-training provider will be audio recorded using the methodology described earlier for recording of the provider baseline visits.

4.4.1 Time Commitment for Provider Participants by Study Phase

The study duration and number of study visits required of provider participants are shown in the table below for each study activity. Note that for Phase I for both providers and patients, the socio-demographic survey will be completed at the same visit as the qualitative interview or mock training. Providers' interview or mock training sessions will occur at a time when providers are routinely in the clinic or in their offices and do not therefore require a special visit. However, as mentioned previously, 8-16 visits will be recorded with each provider at both baseline (pre-training) and during the patient training visits, totaling 16-32 audio recorded visits for each provider (these numbers are approximate because they depend on individual clinicians' clinic schedules and availability of eligible patients). There is no follow-up in Phase I. The only additional visits necessary for providers to make outside of their regularly occurring schedule are for the in-person component of the training; the educational component can be completed individually at the provider's convenience. In Phase III, providers who did not previously participate in Phase II (and thus have no prior survey data) will be asked to complete a brief socio-demographic survey before recording their first clinic visit.

Time Commitment for Provider Participants by Study Phase				
Study Phase	**Activity**	**# Study Visits**	**Duration of Activity**	**Total Duration for Participants**
Phase I (Qualitative Study)	- Socio-demographic Survey - Qualitative Interview OR Mock Training	1 - -	5 minutes 45 minutes 60-90 minutes	60-90 minutes
Phase II (Provider Training Study)	- Pre-Training Survey - Training: Educational Component - Training: In-person Component - Post-Training Survey - Clinic encounter communication assessment/audio recording (8-16 per provider at baseline; post-training) - 1-Month Follow-up Survey - 6-Month Follow-up Survey	1 - - - - 0	15 minutes 60 minutes 60 minutes 20 minutes Minimal additional time 20 minutes 20 minutes	≤ 18 months
Phase III	- Audio recordings of clinic visits	0	Minimal	

(Patient Training Study)	(16 patients) - Socio-demographic Survey (if provider has not previously completed as part of Phase II baseline)		additional time 5 minutes	12-18 months

4.4.2. Time Commitment for Patient Participants by Study Phase

The study duration and number of study visits required of patient participants are shown in the table below for each study activity.

Time Commitment for Patient Participants by Study Phase				
Study Phase	**Activity**	**# Study Visits**	**Duration**	**Total Duration for Participants**
Phase I (Qualitative Study) or Exploratory Focus Groups	- Socio-demographic survey - Focus Groups or interview OR Mock Training/Cognitive Interview	1 - -	5 minutes 90 minutes/ 45 minutes 60-90 minutes	60-90 minutes
Phase II (Provider Training Study)	- Clinic visit communication assessment - Post-Clinic Visit Survey	1 -	5 minutes No additional time for study	60 minutes
Phase III (Patient Training Study)	- Pre-Training Survey - Intervention - Clinic visit audio recorded - Post-Training Survey - 2-Month Follow-up Survey	1 - - - -	46 minutes 30 minutes No additional time for study 31 minutes 41 minutes	$\leq$ 3 months

5.0 Risks to Participants

This study involves participation in qualitative focus groups or interviews, or participation in a behavioral intervention study with minimally invasive assessments (e.g., self-report, collection of audio-recorded clinic visits). The major risks for study subjects are (1) discomfort at answering study questions or during discussions with providers, (2) loss of privacy or confidentiality. Due to the protections we will have in place, we believe these risks to be minimal. There are no procedures that will be conducted as part of the study.

Provider participants will be assured that their participation or the content of their audio recorded clinic visits with patients will not affect their employment in any way. Further, all efforts will be made to conduct the audio recording study with minimal interference to providers' clinical care. We are also making it possible that a clinician can participate even if they do not allow audio recording of their patient encounters.

We are concerned with ensuring that study questions pertaining to sexuality are handled in a sensitive manner. We have chosen standardized sexuality assessment tools that have been widely used and validated to every extent possible, and have made every attempt to ensure that the sexuality items used in the current study are minimally intrusive and highly appropriate. If patients do not want to answer the screening question assessing their degree of sexual concerns or discuss this topic further, they may choose not to answer this question and not to participate in the qualitative or patient training studies (Phases I/III). They will also be informed as to the nature of the items in the study that will be asked of them, and will be assured in the consent forms that they do not have to answer any questions that make them

uncomfortable. We will make it clear that whether or not they answer the screening items or agree to participate in the research study will not affect their care.

6.0 Potential Benefits to Participants

It is possible that the provider and patient training programs will improve providers' and patients' communication skills, and therefore have a beneficial effect on patient-provider interactions, relationships and/or patient health, but this cannot be guaranteed and this will not benefit patients whose providers have not yet participated in the provider training program (i.e., during the qualitative study and the provider baseline phase). Patients receiving the Skills-based training program (Phase III) may also experience benefits including in their interactions with providers and in their relationships or health but this will not affect patients who have not participated in this program (i.e., during the provider training study; patients randomized to the control condition). Patients in either condition in Phase III may learn more about the effects of breast cancer on menopausal and sexual health after reading through the resources. Findings from this study may inform future research on patient-provider communication and sexuality in breast cancer as well as interventions to improve the quality of care for patients with breast cancer and other types of cancer or medical conditions. The minimal risks to subjects are reasonable in relation to potential benefit in improving the care of cancer patients.

7.0 Provisions to Maintain the Confidentiality of Data

In order to minimize the risks associated with discomfort in answering questions, participants will be told that they do not have to answer any research questions and that, if they change their mind about participating, they can stop at any time. All participants (patients and providers) will also be assured that they can stop the audio recording of the encounter at any time, if applicable. All information collected for this study will be kept confidential. Subjects will be told that all information will be kept in strict confidence. All data will be stored on computer files or in locked filing cabinets to which only select members of the research staff will have access. All patient discussions about the study and training sessions will occur in private areas or over the telephone. In order to minimize the risks associated with loss of confidentiality, all patient data (including audio recordings and audio transcripts) will be kept confidential and secure, will be de-identified for analytic purposes, and none of the patients' information will be released to their physician, health care organization, or any other third party without the patient's permission, except as required by law. All audio recordings will be destroyed when analyses are complete or later, if necessary to comply with regulatory authorities.

8.0 Costs to Participants

There are no costs to participants for their participation in the study. The cost of parking, if necessary, will be reimbursed.

9.0 Consent Process

9.1. Consent Process for Provider Participants

Consent from provider participants will be obtained at the following time points: For Phase I (Qualitative Study), in-person immediately before the individual qualitative interview, in the location where the qualitative interview/mock training will be held, by the PI or other consent designee; for Phase II (Provider Training Study), at a convenient time for the provider and in all cases prior to completion of the baseline survey and first clinic visit assessment, by the PI or other consent designee. Participation in Phase III (Patient Training Study) will be included in a separate consent form so as not to confuse participants about what is entailed in their participation. Only English speaking providers will be enrolled.

9.2. Consent Process for Patient Participants

Consent from patient participants will be obtained in written form by an IRB-approved consent designee: For Phase I (Qualitative Study) or the exploratory focus groups, in-person immediately before the focus group/interview, or mock training/cognitive interview at the location where the focus group/interview or mock training/cognitive interview will be held (i.e., a private conference room or other private location on site); for Phase II (Provider Training Study) in-person

before the clinic visit in a private location such as a private clinic room or in a quiet space within the waiting area (or in the case of non-audio recorded clinic encounters, potentially following the clinic encounter); for Phase III (Patient Training Study), electronic consent will be obtained through RedCap or, for patients with no computer access, written consent will be obtained in person or through the mail. Only English speaking patients will be enrolled. Participants will be given time to ask questions privately before they sign consent forms.

10.0 Off-Study Criteria

Any participant may leave the study at any time due to distress or other reasons. It is possible, though very unlikely, that a participant in the focus group might become unruly or disruptive, in which case she would be asked to stop participation. For Phase II and III, a clinician participant may change his or her preference for having the clinic encounters audio recorded, and this will not necessitate leaving the study, although we will have the clinician indicate his or her new preferences in the consent form.

11.0 Drugs and Devices

Not applicable.

12.0 Multi-Site Research Study

Not applicable.

13.0 Statistical Analysis

13.1. Statistical Analyses for Qualitative Study (Phase I) and Exploratory Aim

13.1.1. Primary and Secondary Outcome Variables

Our primary analysis for this study is exploratory using qualitative methods and as such, there are no primary or secondary outcome variables.

13.1.2. Analyses

Demographic information from participants will be analyzed using descriptive statistics (e.g., frequencies, means, variances) to ascertain relevant characteristics of the study group. Primary analyses will be qualitative. Qualitative interviews and focus groups will be transcribed to allow for coding of the dialogue. Data from qualitative interviews and focus groups will be analyzed using qualitative software, which allows text to be coded into a hierarchical, branching structure that first identifies broad concepts, followed by themes and variations within those constructs. Data analysis will utilize a grounded theory approach, in which theory is derived from the data, and new theoretical categories are derived until they are "saturated" and further insights do not emerge.[84] In this theoretical approach, the researcher interprets and labels verbatim quotes pertaining to the subject under inquiry (i.e., "raw data") and codes concepts that form the basic units of analysis. Concepts that pertain to similar phenomena are then classified into categories which provide the cornerstones of a developing theory. Finally, through constantly comparing concepts and categories, analyzing data for patterns, and testing and revising hypotheses, a theory emerges from the data. Another approach that may also be utilized, depending on the fit with the data, is the framework approach to qualitative analysis,[85] which is useful for targeted qualitative studies, as the exploratory focus groups are in the current study (e.g., in developing an intervention rather than serving to develop a unified generalizable theory). Dr. Reese has familiarity in conducting qualitative analysis and will utilize the expertise of other research team members in coding the data. Two coders will code and/or discuss all data and differences will be resolved through discussion. Regular meetings among the qualitative coding team will be held to ensure a high level of quality for the qualitative analysis. Mock training and cognitive interview notes will be examined descriptively rather than using grounded theory methods. Study team meetings will help translate the findings of the qualitative focus groups and interviews to intervention content drafts; these will be reviewed and finalized through an iterative process utilizing appropriate expertise within the study team.

13.2. Outcomes and Statistical Analyses for Provider Training Study (Phase II)

13.2.1. Primary Outcomes

(1) providers' **self-efficacy** and **outcome expectancies** for communicating about sexual concerns (physical, motivational/emotional, or either) on a 0-10 point Likert scale where 0=not at all confident or will not improve at all and 10=extremely confident or will improve a lot,
(2) **frequency of 2 critical provider behaviors**[86,87] per visit obtained from audio recordings: (a) Asking a question about sexual concerns, and (b) Offering information/counseling pertaining to sexual concerns, and
(3) 2 aspects of **quality of communication**: (a) Complexity (i.e., number of target behaviors provider engaged in; and (b) Length of discussion about sexual concerns (in seconds), obtained through audio recorded sessions.

13.2.2. Secondary Outcomes

(1) Patient satisfaction (rated after visits; self-report)
(2) Missed opportunities for communication about sex (defined in the paragraph below)
(3) Providers' barriers to communication about sexual health (self-report)[68]
(4) Two additional communication behaviors coded from audio recordings: (a) raising the topic of sexual health (clinician initiated the discussion) and (2) Raising the topic with counseling (e.g., "Many women on this treatment experience sexual concerns")

13.2.3. Analyses

Because there is no existing validated dialogue coding scheme for patient-provider discussions of sexual issues, the dialogue coding will be conducted largely through the generation of a new code book which will be able to be applied to subsequent data sets. Audio recorded dialogue will be coded using the following three methods, through N Vivo or similar software program that can be used to analyze verbal communication data, such as SPSS: 1) Dr. Reese will work with Dr. Beach, a patient-provider interaction coding expert and mentor on the PI's MRSG, to develop a sexuality dialogue codebook. We will code physical sexual concerns as pertaining to performance of sex (e.g., lubrication, orgasm, discomfort), fertility-related concerns, and motivational/emotional concerns (e.g., desire, satisfaction, enjoyment, intimacy, body image, and femininity).[9,19,28,36] 2) Frequency and quality of provider sexual communication behaviors (primary outcomes listed above) will be coded, as well as other provider and patient communication behaviors that are of interest (e.g., patient question asking), using qualitative methods to draw out behaviors from the dialogue data. We will also code **"missed opportunities" for communication about sex** based on (a) coding patient cues not pursued by providers[88] (e.g., "I wasn't told how this would affect my sexual function") or reporting of symptoms/side effects known to effect sexuality (e.g., menopausal symptoms) that could serve as a cue for providers to discuss sexual issues; and/or (b) considering patients who score > 0 on the PCM sexual concerns screening item but for whom sexual concerns are not discussed in their clinic visit, according to their self-report, a missed cue. 3) We may also code for discussions of other common patient complaints including pain and fatigue; these offer interesting comparators with sexual concerns in terms of the frequency and complexity of discussions. The dialogue will be coded in two stages, first for the presence of any discussions of sexual health (and related health issues), and secondarily, for the more detailed codes generated in the codebook. In order to develop the codebook mentioned above, Dr. Reese and Dr. Beach will analyze the baseline set of encounters until a codebook is generated, and Dr. Reese will apply these codes to the encounters. To ensure that discussions of sexual health are not missed, a trained coder will code a random 20% of the transcripts to ensure inter-rater reliability, unless two coders code all data. Regular meetings will be held to discuss definition changes and coding problems and to resolve any inconsistencies. We will consider inter-rater reliability of $\geq$.60 on our key outcomes to be adequate based on prior research.[89] Dialogue will be analyzed through transcripts of the audio recordings. A first analysis will characterize the communication at baseline (pre-provider training). The next set of analyses will concern the changes proposed through the intervention.

Descriptive analyses (e.g., frequencies, measures of central tendency) will determine the feasibility and acceptability of the training program. Seventy-five percent of participants rating the training program favorably ("Agree"/"Strongly

Agree" or "Satisfied"/"Very Satisfied") on study evaluations will be considered adequate acceptability. Patients at baseline and post-intervention will be compared on socio-demographic and medical variables using Chi-square tests or t-tests. Pilot efficacy analyses will be calculated through the following method. Mean differences will be calculated in self-report outcome measures at baseline and 6-month follow-up as the final endpoint, along with standard deviations and the effect size (mean difference/SD of the differences). Regarding the communication outcomes, if audio recordings are available, those data will be used. If there appear to be significant differences between the audio recorded and the self-report communication data, separate analyses may be conducted for these two types of data. Clinician communication outcomes will be examined descriptively by comparing the proportions of clinic visits in which the target communication behaviors occurred at post-intervention versus baseline. Additionally, we will conduct exploratory analyses on the communication variables where the effect of post-intervention was evaluated using generalized linear models with robust standard errors via Generalized Estimating Equations to account for within-provider correlation. Specifically, logistic regression will be used to examine binary outcomes, Poisson regression will be used to examine length of discussion about sexual health and a risk ratio presented for this variable (no discussion was coded as zero seconds), and ordinal logistic regression will be used to examine intervention effects on complexity of communication (categorized as 0, 1, or 2) and on patient satisfaction. Although the study was not powered for formal comparisons, we will consider presenting the model based estimates of effect sizes and corresponding 95% confidence intervals.

Additional analyses will concern the validation of the patient communication self-report measure that we have developed to supplement, and in some cases replace, the audio recorded dialogue obtained from clinic encounters. A major part of this analysis will be to examine how well the audio recorded and self-report communication outcome measures correlate using kappa calculations or other appropriate statistical tests for agreement.

13.2.4. Sample Size Calculations

Because the objective of the Provider Training Study (Phase II) is to pilot test the newly developed provider training intervention, we do not conduct sample size calculations for this phase of the study, with the sample of 6-8 providers chosen based on what is feasible to accomplish in a pilot. Instead, sample size justification is provided below for the Patient Training Study. We will calculate pre-post effect sizes to inform a larger R01 trial that is expected to follow from this study.

13.3. Outcomes and Statistical Analyses for Patient Training Study (Phase III)

13.3.1. Primary Outcomes

(1) Patients' **self-efficacy** and **outcome expectancies** for communicating about sexual health with their provider, and
(2) (A) The **proportion of visits in which the patient asks at least one question pertaining to sexual health**, and (B) the **proportion of clinic visits in which the patient raises the topic of sexual health,** both at post-training clinic visit

13.3.2. Secondary Outcomes

(1) Feasibility and acceptability, as measured through recruitment and retention rates, and by acceptable responses on the Program Evaluation
(2) Sexual function, as measured through the PROMIS SexFS Brief Profile (Female) score
(3) Sexual activity, as measured through a single item on the PROMIS SexFS Brief Profile (Female)
(4) Patients' self-efficacy (measured via the PEPPI-5 and 6 additional self-efficacy items) and outcome expectancies for communicating about treatment side effects in general and menopausal health with their provider,
(5) Patients' self-reports of barriers to communicating about sexual health
(6) Patient self-reports of psychological health (Hospital Anxiety and Depression scores)
(7) Patient self-reports of QOL (FACT-B total score)

An exploratory outcome may also be the number of questions a patient asks overall per visit. Additional outcomes are shown in the Patient Training Study Patient Self-Report Measures Table. Data will be obtained on these other measures

to generate hypotheses which can be tested in future studies and will be analyzed according to standard procedures, similar to those described for the main outcomes as below.

13.3.3. Analyses

Primary Analyses

Prior to conducting primary analyses, we will generate summaries of all variables. Demographic and medical variables will be summarized using descriptive statistics (means, medians, standard deviations, frequencies, proportion missing, etc.). We will assess the distribution of all continuous measures (particularly outcome measures), and if appropriate, normalizing transformations will be applied.

Generalized linear mixed models with appropriate link and variance functions will test for the effects of patient training on beliefs (self-efficacy, outcome expectancies) over time. We will include intervention arm, indicators for timepoint (T2 and T3 vs T2), and an interaction between time and treatment arm. If the interaction between time and treatment arm is significantly different from zero, we will conclude that the intervention influenced beliefs at follow-up (T2/T3). If linear regression models are appropriate, stratification factors (disease stage, education) will be included as covariates to reduce variance. We will use nested random effects (times within patients, patients within providers) to account for multiple sources of correlation.

Prior to conducting quantitative analyses, the audio recorded clinic visits will be coded, using a similar strategy as described for the Provider Training Study (Phase II), which centers on the newly developed sexuality dialogue codebook, but can also include other communication behaviors or topics that emerge as important through the coding analyses. To test the hypothesis that patient communication behaviors differ for those in the Skills-based vs. Control conditions, we will use Fisher's exact tests. If a patient asks 1 or more questions during the visit, they will be coded as "yes" for outcome 2A and "no" otherwise. If a patient brings up the topic of sexual health they will be coded as "yes" for outcome 2B. If no one brings up the topic of sexual health, they will be coded as "no". If the provider brings up sexual health, these visits will be excluded from analysis of outcome 2B, as it is impossible to know if the patient may have brought up sexual health if the doctor had not done so. In preliminary data from phase II, these communication behaviors were so rare that Fisher's exact tests will be primarily used. If possible, we will also conduct logistic regression analyses accounting for within-provider correlation using random effects (estimated via generalized linear mixed models, similar to the models described above).

In supplementary analyses, we may examine patient factors that may moderate effects on patient outcomes (e.g., age, partnered status, metastatic disease) by including the moderator, study arm, and study arm by moderator interaction terms in generalized linear mixed models. We may also conduct secondary regression analyses to verify the conclusions of primary models, to assess the sensitivity of inferences to the assumptions of the mixed effects models. For example, we may use Generalized Estimating Equations as confirmatory models, or use logistic or ordinal logistic regressions if the semi-continuous outcome measures cannot be transformed so that the assumptions of the linear regression model are met.

Secondary Analyses

Feasibility and acceptability of the intervention will be analyzed using descriptive analyses. Recruitment rate is operationalized as the proportion of screened and eligible candidates who choose to enroll on the study. Based on our other sexuality trials, a recruitment rate of $\geq$ 30% will be considered acceptable. Retention is operationalized separately as the proportion of enrolled study subjects who end up completing all study surveys. A retention rate $\geq$ 70% will be considered adequate. Acceptability is measured through scores on responses to items in the Program Evaluation form. If $\geq$ 75% of participants indicate "Satisfied" or "Very satisfied" on item 15 of this scale (the overall satisfaction item) at post-treatment, that will indicate adequate overall acceptability of the program. Other items on this scale will also be

analyzed descriptively and the information will supplement about the other data points on the acceptability of the program.

We will also determine whether the skills-based program effected pre-post differences (T3 – T1) for the secondary outcomes of: sexual function, sexual activity (active vs. not active), patients' communication self-efficacy and outcome expectancies, patients' self-reports of barriers to communicating about sexual health, and patient self-reports of psychological health (Hospital Anxiety and Depression scores) and patient self-reports of QOL (FACT-B total score). Similar to the analyses conducted for primary outcome 1, we will use generalized linear mixed models or hierarchical logistic regression models (if outcome is dichotomous), to determine the effect of the intervention arm on these measures. T2-T1 differences will also be analyzed for the beliefs measures.

Exploratory Analyses

If possible, exploratory analyses will be conducted, where we will look at the number of questions patients ask per visit. We will use Poisson or Negative Binomial models for these count outcomes, and will consider zero-inflated models if appropriate. Additional analyses of other exploratory measures will be conducted using generalized linear mixed models, similar to those performed for Primary aim 1. Also, we will explore potential mediation effects, specifically, whether self-efficacy mediates the intervention effect on belief outcomes. We do not anticipate sufficient power for a formal mediation analysis, but we will gather preliminary estimates of effect sizes which may be used to design future studies.

13.3.4. Sample Size Calculations

The sample size calculations are based on the primary belief outcomes. Based on prior literature,[90] we assume a standard effect size of .60 on the outcome of patient beliefs. We therefore aim to accrue up to 144 patients (72 per arm) in order to collect an estimated 128 audio recordings (64 per arm) to have 80% power to detect a standard effect of 0.5, with 5% two-sided type-I error.

Other primary outcomes include A) the proportion of visits where the patient asks a question, and B) the proportion of visits where the patient brings up sexual health. Based on preliminary data, we expect these proportions to be low in the control arm (15% and 22%, respectively). We also anticipate that 70% of visits will be informative for outcome B (only visits where the physician does NOT bring up sexual health to be included). Therefore, with sample size of 128 audio recordings, we will have 80% power with 5% 2-sided type-I error to detect rates of 38% for outcome A in the intervention arm versus 15% in the control arm (calculations using Fisher's exact test). For outcome B, assuming 45 informative visits per arm, we will have sufficient power to detect rates of 52% in the intervention arm versus 22% in the control arm.

14.0. Data Safety Monitoring Plan

The PI will take responsibility for monitoring the safety of all phases of the research study. The research assistant or other study staff will report any adverse events they observe to the PI within 24 hours. The patient consent form will contain the contact information for the PI and the Institutional Review Board (IRB), and state that patients may contact her or the IRB at any time. Clinician subjects will also have the contact information for the IRB and can report issues to either of these resources. A DSMB is not required for the current study.

15.0. Adverse Event Reporting

Because of the nature of the research as involving procedures without significant risk (e.g., qualitative study; surveys; brief communication skills training programs; audio recorded clinic visits) there are unlikely to be any serious adverse events and adverse events are likely to be rare. Possible risks include feeling worried, anxious, or concerned during

questionnaire completion or during the intervention sessions. All participants are informed of possible adverse psychological reactions associated with participating in the study during the informed consent process.

Any unexpected or adverse event that occurs during data collection or study procedures is reported immediately to the Principal Investigator, who is responsible for documenting all adverse events with the FCCC IRB within 24 hours. For participants who are experiencing psychological distress reactions, the study team member or research assistant alerts the Principal Investigator, who would provide the participant with a referral to appropriate services. At FCCC counselors in the Department of Social Work are trained to provide psychological support services or to make specific referrals to other psychological counseling or psychiatric services in the area as needed.

The research team will keep a log tracking the number, nature, and frequency of adverse events as part of each phase of the research plan. In accordance with FCCC guidelines, this protocol will employ the following mechanisms for adverse event reporting: 1) alert the FCCC review committees of any and all reports of adverse events; 2) inform all members of the study team of any all reports of adverse events. If 3 or more adverse events are reported, the study team will assess potential causes of the adverse events and, if events are clearly linked to study participation, discontinue the study.

16.0. Quality Assurance Procedures and Participant Confidentiality

16.1 Quality Assurance Procedures

Quality assurance is particularly important for the study phases involving the interventions (Phases II and III). Interventionist training and quality assurance procedures will follow empirically-supported methods,[91] which include maintaining manuals and structured procedures by which the intervention is conducted. To ensure quality of both conditions in Phase III, the interventionist will (a) undergo rigorous training and testing procedures supervised by Dr. Reese and her mentors; (b) record length of time spent delivering the protocols to ensure approximate equivalency of time spent with patients across both conditions; (c) complete checklists testing compliance with all protocol activities as specified in the manual; and (d) participate in weekly supervision with Dr. Reese, who has experience with patient-focused interventions.[65,66] Supervision will help limit drift from the protocol and resolve any issues in delivery of the intervention. Meetings with Drs. Lepore and Beach will resolve unresolved or complex issues.

16.2 Participant Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations required a signed subject authorization informing the subject of the following: The protected health information (PHI) that will be collected from patient; who will have access to that information and why; who will use or disclose that information; the rights of a research subject to revoke their authorization or use their PHI. In the event that a participant revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information prior to the revocation of subject authorization. To ensure confidentiality identifiers will be recorded and used with electronic data collected and all records will be secured in a locked location. Audio recordings will be transferred immediately to an electronic file with access allowed only to the PI and members of the research team and removed from the recording device as soon as they are transferred.

All initial contacts with patient participants will be conducted with approval by the patient's treating physician and will be from a research team member or the patient's treating physician, unless the patient calls in response to an advertisement. Therefore, a request for waiver of HIPAA authorization has not been submitted. We will identify potentially eligible recruits through the electronic medical record or the Fox Chase Cancer Registry. We have a number of safeguards in place to protect the PHI of individuals who may be recruited for this study and the disclosure of the PHI we request involves no more than minimal risk to the privacy of individuals. Only study recruiters or the PI will have access to the identifiers, and this information will be kept in a secure password-protected electronic file. In order to send

introductory letters to study candidates and allow them to opt out of the study, obtaining the contact information is necessary prior to enrollment.

17.0. Participant Informed Consent

For Phase I, see Phase I Informed Consent documents in Appendix A. Separate documents exist for providers and patients, and for participation in the qualitative interview/focus group and mock trainings/cognitive interviews. Note that for the qualitative focus groups and interviews (patients) and interviews (providers) the consent form indicates agreement to have this discussion audio recorded. This is necessary in order to code the data later for qualitative themes, and because note-taking alone would not suffice in facilitating such coding. For the focus group, in particular, all participants must agree to have the group discussion audio recorded because the discussion cannot be recorded for some participants and not others.

For Phase II, provider participants will sign written consent after being approached for the study which will include consent to complete self-report surveys before the intervention, and at post-intervention, and 1- and 6-month follow-up, to allow us to assess, and possibly audio record a number of their clinic encounters (8-16 per provider at baseline and post-intervention), and to participate in the brief intervention. Provider consents will have an option to consent to the audio recording of their clinic visits. In the case that fellows, nurses, students, or other third parties are involved in the clinic encounters of provider participants, they will sign a separate consent for the audio recording of their portion of the relevant clinic visits. Phase II patient participants will sign a separate consent document that includes completing the study survey, and allowing us to audio record their clinic visit, if applicable. Patients in Phase II will indicate their permission to have us audio record their clinic visit on their consent form. There will also be a section on the patient informed consent form for third parties (family members, significant others, etc.) to consent to be audio recorded, should they be present during the recorded clinic visit. Third parties will not be considered study participants.

For Phase III, patient participants will sign electronic or written consent (depending on internet access) prior to completing the baseline survey. On this form, patients will also consent to the audio recording of their upcoming clinic visit. At the time of the patient's clinic visit, if a third party (family member, significant other, etc.) is present, the third party will be asked to sign a separate consent giving permission to be audio recorded during the clinic visit. Provider participants will sign written consent for clinic visit audio recordings prior to initiating patient recruitment. Third party clinicians who may be recorded (e.g., fellows, nurses) will be asked to sign a consent form as well. As with Phase II, third parties will not be considered study participants.

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19.0. Appendices

Appendix A. Consent Forms (Patient Focus Group Consent, Patient Mock Training Consent, Provider Qualitative Interview Consent, Provider Mock Training Consent) and HIPAA Authorization Form

Appendix B. Self-Report Measures (Patient Demographic Survey, Provider Demographic Survey)

Appendix C. Recruitment Materials (Patient Screening Script, Focus Group recruitment letter, Mock training recruitment letter, Focus Group flyer, Provider informational handout)