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Protocol Title

Enhancing Clinical Communication about Sexual Health for Women with Gynecologic Cancer: Adaptation of a Multimedia Intervention

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1.0 Introduction

Background: Treatments for gynecologic cancer, including surgery, chemotherapy, and pelvic radiation, extend women's survival but often at the cost of impaired sexual function,[1-4] with over half of gynecologic cancer survivors reporting sexual problems after treatment.[1,5-7] Common sexual problems include those that are physiological (e.g., vaginal dryness/pain, arousal difficulties),[4,8,9] emotional/motivational (e.g., loss of sexual desire, body image concerns),[8,10,11] and interpersonal in nature (e.g., sexual inactivity with partner).[8,11-13] For women with gynecologic cancer, unaddressed sexual problems often persist years after treatment concludes,[14] leading to distress[15] and compromised quality of life (**QOL**).[15-17] Yet even though sexual function is included in current clinical practice guidelines in oncology,[18-20] such concerns are surprisingly neglected in the care of women with gynecologic cancers.[21] The vast majority (62-87%) of women with gynecologic cancer report no discussion of sexual health occurring during their cancer care,[22-24] and only 35% of gynecologic cancer patients who report sexual problems actually initiate a discussion about this issue with their clinician.[25] These data are at odds with the commonly held belief that women with cancer will raise sexual health when experiencing problems.[26] Rather, women with gynecologic cancer face formidable barriers to discussing sexual health with their clinicians, including a lack of preparation and skills deficits.[5,25,27-29] Interventions that foster effective patient communication could prove critical in the effort to integrate sexual health into cancer care for women with gynecologic cancer, yet no such interventions have been designed or tested.

To address this gap, we propose to evaluate a multimedia intervention, called Starting the Conversation (**STC**), aimed at facilitating effective clinical communication about sexual health concerns. We recently found strong evidence supporting this intervention in a controlled trial in women with breast cancer (N=144).[30] Women receiving the STC intervention [30-minute skills training video, workbook, and resource guide] had nearly three-times greater odds of discussing sexual health during a routine clinic encounter with their cancer clinician than women receiving the resource guide alone, while also showing improvements in their self-efficacy (i.e., confidence) for discussing sexual concerns, and for sexual and psychological outcomes.[30] We expect that the STC intervention will be effective in women with gynecologic cancer, who report similar rates and types of sexual problems[31,32] and similar challenges to discussing sexual health as women with breast cancer.[27,33] Using expert input and extensive literature review, we have adapted this intervention to gynecologic cancer and now plan to collect pilot data on this adapted that will support the funding of a larger clinical trial of this intervention in this new population.

2.0 Objectives

The central goal of this study is to examine the feasibility, acceptability, and preliminary efficacy of the newly adapted STC intervention on patient-clinician communication about sexual health. However, there are additional issues that are understudied and could be informative to the design of a larger trial that we intend to examine through three exploratory aims. First, although we know that sexual health discussions be held for gynecologic cancer patients who are partnered and unpartnered, there is little information known about how women's partnered status might influence the appropriateness or efficacy of the STC intervention. Thus, in an exploratory aim, we will examine whether women's partnered status is associated with the feasibility, acceptability or preliminary effects of the STC intervention with any of the study outcomes. As level of sexual concerns may also play a role, we will examine that along with partnered status. We expect that the information we collect on partner participation and the preferences regarding this will be informative for our larger trial.

Specific Aim 1. To assess the feasibility and acceptability of the STC intervention in a pilot study in women with gynecologic cancer.

Hypothesis 1. STC will be judged as feasible, determined through measures of rates of participant enrollment, retention, and intervention completion.

Hypothesis 2. STC will be judged as acceptable, determined through post-intervention evaluations of intervention satisfaction, informativeness, relevance, helpfulness, ease of participation, approval of the format, likelihood of recommending to others, and perceived importance of the program for people with gynecologic cancer.

Specific Aim 2. To assess the preliminary effects of the STC intervention on patient-clinician communication about sexual health and on patients' sexual and psychological health outcomes.

Hypothesis 3. STC will show positive effects on patients' self-efficacy for clinical communication about sexual health concerns from baseline to post-intervention and 2-month follow-up, and their clinical communication about sexual health concerns (discussing sexual health concerns; raising the topic; asking a question about sexual health) at their post-intervention clinic encounter.

Hypothesis 4. STC will show positive effects on patients' sexual function, activity, and psychological distress from baseline to 2-month follow-up.

Exploratory Aim 1. To explore the feasibility, acceptability, and preliminary effects of the STC intervention by women's partnered status and level of sexual concerns. Additionally, exploratory analyses will examine baseline body compassion,[34] a concept meaning acceptance and compassion toward the physical body, which is associated with psychological health outcomes in gynecological populations. As a relatively new measure within cancer survivorship research, we will examine baseline scores on this measure in a hypothesis-generating fashion to inform future research studies.

3.0 Background/Rationale

With 113,520 new cases in 2020, gynecologic cancer (ovarian, uterine/endometrial, cervical, vaginal/vulvar), ranks behind breast cancer but ahead of lung and colorectal cancer in terms of number of new cases diagnosed for women in the U.S.[35] When diagnosed with local disease, >90% of women with gynecologic cancer survive at least 5 years, and survival is improving overall.[35] While critical to extending survival, the treatments commonly used for gynecologic cancer, including surgeries (e.g., hysterectomy; bilateral salpingo-oophorectomy; **BSO**), chemotherapy, and pelvic radiation lead to sexual problems for women;[1-7,12] as many as 87-89% of gynecologic cancer survivors report experiencing negative consequences to their sexual health, here defined as including sexual activity, function, body image, and intimate relationship)[30,36] resulting from their treatment(s).[1,2] Common sexual problems include those that are physiological (e.g., vaginal dryness, pain during sexual activity),[1,5,7,9,37,38] emotional/motivational (e.g., loss of libido, anxiety about having sex, body/self-image image changes),[10,11,37-40] and interpersonal in nature (decreased sexual activity, relationship issues).[11-13,38,41,42] These difficulties tend to persist over time, with gynecologic cancer survivors up to 7 years post-treatment reporting greater frequency and severity of sexual problems than women with no cancer history.[39,42-45] Women treated for gynecologic

cancer often report feeling grief over their loss of sexual enjoyment, underscoring how cancer-related sexual problems compromise their quality of life (**QOL**)[15-17] and impact their relationships for the worse.[42]

Despite the large body of research establishing sexual function as distressing for women with gynecologic cancer,[12,22,29,41,46-48] and the fact that current clinical practice guidelines universally encourage cancer-related sexual health to be included in routine clinical care for cancer survivors, alongside pain, fatigue, and other health issues,[19,20] fewer than half of women with gynecologic cancer report that they have ever had a discussion with their clinical provider about sexual issues.[30,49-52] Only 23-40% of women with gynecologic cancer report receiving information about potential sexual side effects of their treatments.[24,49,53] This lack of discussion compromises women's ability to manage sexual problems when they occur. For instance, in a study of women attending a vulvovaginal health clinic (N=146; 26% gynecologic cancer), over half of patients with *moderate to severe vaginal dryness* reported "never" using vaginal lubricants and moisturizers,[54] which have proven efficacy for ameliorating this problem.[20,55] Yet patients face formidable barriers in raising these issues with their clinicians that undermine their active participation in their care regarding this issue, including lack of preparation, unhelpful beliefs, and emotional discomfort.[28,31,56] Moreover, despite common assumptions that (a) clinicians lack the specialized training needed to manage sexual problems for women with gynecologic cancer and (b) little can be done to address their patients' sexual concerns,[22,57] most women with gynecologic cancer could benefit from brief and focused information about sexual side effects of treatment and on simple effective strategies (e.g., use of vaginal lubricants and moisturizers),[55,58] and/or referrals for sexual problems requiring further assessment and management, which do not require specialized training. Ultimately, the lack of discussion of sexual concerns not only conflicts with recommended guidelines for clinical care but is also out of sync with the preferences of women with gynecologic cancer, most of whom would like sexual concerns to be discussed in their care.[28,31]

In light of the clear and concerning absence of routine clinical discussion of sexual health for women with gynecologic cancer and the substantial patient barriers to discussing these concerns, there is an obvious need for interventions that can effectively promote women's active engagement in their care regarding sexual health concerns. To address this need, we propose to conduct a pilot test of a multimedia intervention, called Starting the Conversation (**STC**), aimed at facilitating effective clinical communication about sexual health for women with gynecologic cancer. This intervention contains focused skills training and practice in a format consisting of a 25-minute mobile-accessible narrated video and accompanying workbook (see **Figure 1**); we found this intervention to be feasible, acceptable and efficacious in a recent study completed in women with any stage breast cancer.[30]

Women often lack awareness of common sexual issues associated with their treatments as well as confidence in knowing how to raise these issues effectively.[28,31,56] A major aim of the proposed intervention is thus to improve participants' confidence, or self-efficacy, in communicating about sexual concerns (**Figure 1**).[59-61] To this end, the study design and intervention are guided by social cognitive theory,[59,60] which emphasizes the importance of fostering self-efficacy in interventions designed to increase behavioral engagement in certain tasks and underlies numerous successful communication interventions.[59,60,62-64] The STC intervention integrates theory-guided skills training and practice, and therefore is likely to be effective in promoting women's active engagement in clinical discussions of sexual health concerns. In addition to a lack of knowledge and skills, there is continuing stigma surrounding discussions of sexual health in clinical care, [26,56] such that many women express timidity in expressing such concerns with their clinicians.[56,65] For this reason, normalizing women's sexual concerns and the importance of discussing sexual health, as well as clarifying expectations for patients' and clinicians' roles in the discussions (e.g., underscoring the expectation that clinicians respond to patients' expressed sexual concerns) could increase patients' comfort and thus lead to greater communication about these issues.[66]

We thus include these elements in the STC intervention. In sum, there is strong support for the content of the STC intervention as potentially efficacious in women with gynecologic cancer.

Patient-focused interventions can significantly improve patients' beliefs and behaviors with respect to clinical communication about health concerns.[67-71] Within oncology, patient-focused interventions that aim to foster an active role for cancer patients in discussing cancer-related health issues such as pain using education and/or skills training have demonstrated efficacy.[63,72] Importantly, even very brief patient-focused interventions (e.g., <1 hour) have shown effects on these outcomes.[69,73] In a successful trial of the STC intervention in women with breast cancer, we found significant effects of the STC intervention on both women's self-efficacy and their communication about sexual health (raising the topic, asking a question) in a routine clinical encounter with their cancer clinician (see C.3.3 for preliminary data).[30] Given that the sexual health communication practice and preferences are highly similar for women with gynecologic and breast cancer,[27,33,74] we expect to ultimately find similar effects for the STC intervention in women with gynecologic cancer.

In addition to improving women's communication about sexual health, preliminary data suggests that such an intervention could also benefit their sexual health outcomes,[30] perhaps because a productive clinical discussion may lead to information or suggestions that help women address sexual concerns and/or be able to engage in sexual activity.[30] We plan to collect information on preliminary effects of the intervention on women's sexual activity and function, which can be responsive to change due to sexuality interventions for women with cancer.[75,76] We found positive effects of STC on women's psychological outcomes, in particular, anxiety. This finding is consistent with research findings showing that positive communication between women and their clinicians and greater feelings of empowerment within women's clinical care are associated with lower patient anxiety.[77] Taken together, these findings suggest that by increasing women's confidence in expressing key health concerns, the STC intervention could help alleviate distress associated with leaving such concerns unaddressed.[30]

Prior studies have shown that certain factors such as age and partnered status might affect sexual concerns and/or preferences for discussions of sexual issues for women with gynecologic cancer.[6,13,28] With respect to medical factors (e.g., disease stage/site), research is inconsistent regarding their effects on sexual function or communication about sexual health after gynecologic cancer, with some studies offering evidence for effects of these factors on sexual outcomes[13,37,39,42,78] and others showing no such effects.[9,15,16,28,40] We will thus examine these factors in an exploratory aim. Findings will inform next steps, which could include examining such factors as potential moderators in a large trial and ultimately potentially tailoring the STC intervention for certain subgroups. In addition, little is known about the involvement of patients' intimate partners into clinical communication interventions around the topic of sexual health or into these discussions themselves. Thus, we plan to examine this in a second exploratory aim, which will be used to guide decisions about inclusion of partners into a larger planned randomized controlled trial.

Preliminary Data

Sexual Concerns for Women with Gynecologic Cancer. Research by Dr. Bober has demonstrated sexual problems to be significant in women with gynecologic cancer, and in particular, ovarian cancer. In a trial testing a sexual function intervention for women with ovarian cancer (N=46; M age=55.8), at baseline, mean Female Sexual Function Index (**FSFI**) scores (13.4; SD=7.3) fell well below the established cut-off for sexual dysfunction of 26.55,[79] suggesting substantial sexual dysfunction within the sample; sexual desire scores (2.3; SD=1.4) were also well-below cut-offs for hypoactive sexual desire disorder of 5.0.[80] Moreover, sexual dysfunction did not improve during a two-month run-in period prior to receiving an

intervention. Importantly, a substantial proportion of the sample in the study (13%) were currently undergoing chemotherapy, suggesting that women with gynecologic cancer who are undergoing active treatment are nevertheless amenable to participating in a sexual health trial.

Patient-Clinician Communication about Sexual Health in Women with Gynecologic Cancer. In a recent systematic review of 29 studies assessing the prevalence of sexual health communication in cancer conducted by the PI (Reese), 10 (34%) of these studies included data from women with gynecologic cancer.[81] It was also reported that female patient gender predicted a lower prevalence of sexual health discussions. Discussions of sexual concerns occurred for only 14-47% of women;[22,23,50] discussion of potential sexual side effects of treatment, specifically, occurred for 23-40%.[24,49,53] These data demonstrate that discussions of sexual concerns in women with gynecologic cancer are rare and that interventions are needed to help close this gap in women's clinical care.

Improving Sexual Health Communication for Women with Cancer. In a recent study funded by the PI's ACS Mentored Research Scholar Grant, women with breast cancer (N=144) were randomly assigned to either the STC intervention [20-minute video, workbook, and resource guide] or a control [resource guide only]. Analyzing the communication from patients' next clinic encounter following receipt of either the intervention or control material revealed that women in the STC arm were significantly more likely to raise the topic of sexual health [51%; OR=2.62(1.02, 6.69), *p*=.04] and ask a sexual health question [40%; OR=2.85(1.27, 6.38), *p*=.01] during their clinic encounter than those in the control arm (30% and 19% for raise and ask, respectively). Further, at 2-month follow-up, we found that women in the STC arm showed greater improvements in sexual health communication self-efficacy (*p*=.009) and in anxiety symptoms (*p*=.03), and more women were sexually active at follow-up, compared to the control arm (OR=1.5, 70% vs. 46%, *p*=.04). Additionally, high rates of enrollment (88%) and retention (97%) were seen, with notable enrollment by women from racial/ethnic minorities. Specifically, 27% of the sample self-identified as Black/African-American, 6% identified as bi-racial/ "other," and 4% identified as Hispanic/Latina, supporting the acceptability and efficacy of the STC intervention in women from a range of racial and ethnic backgrounds. Further, 15% percent of the sample had a diagnosis of metastatic cancer and 33% were unpartnered, supporting the appropriateness of the material to women across different stages of disease and relationship status. Finally, women reported high rates of using the video and workbook (rates >85%), suggesting high engagement with the study materials across conditions; responses to open-ended questions in the post-study surveys further supported acceptability. In sum, these data suggest that the STC intervention is feasible, acceptable, and has significant positive effects for diverse clinical communication and health outcomes in a sample of women with breast cancer.

In sum, sexual concerns for gynecologic cancer survivors are inadequately addressed in clinical care. In this pilot study, we propose to assess the feasibility, acceptability, and preliminary effects of a brief multimedia intervention designed to facilitate gynecologic cancer patients' effective communication about sexual health concerns. The data we collect from this study will directly inform the design of a larger planned randomized controlled trial, which will determine the intervention's efficacy in this population.

4.0 Study Design

4.1 Overall Study Design

In this pilot study, 30-36 women with a diagnosis of any stage gynecologic cancer will be randomized 2:1 to either the Starting the Conversation (STC) condition, a multimedia intervention aimed at enhancing sexual health communication consisting of a skill-building video and workbook with a resource guide, or

to a control condition offering the resource guide only. We may randomize up to 36 patients in the event that some participants are unable to provide communication data (e.g., due to attrition or cancellation of clinic visits), with the goal of collecting clinic communication data on 30 women. The objective of this study is assess feasibility, acceptability, and preliminary effects of the STC intervention, in an effort to guide the design of a larger planned randomized controlled trial to determine intervention efficacy. Feasibility will be measured through rates of study enrollment, retention, and intervention completion. Acceptability will be assessed through post-intervention evaluations of intervention satisfaction, informativeness, relevance, helpfulness, ease of participation, approval of the format, likelihood of recommending to others, and perceived importance of the program for people with gynecologic cancer. Preliminary efficacy will be assessed through estimating the intervention effect size, if appropriate, or through looking descriptively at means and confidence intervals on improved. In Aim 2, validated self-report measures will assess intervention-related change in patients' self-efficacy for sexual health communication and sexual and psychological health outcomes from baseline to to 2-month follow-up. Data for exploratory aims will be assessed using patients' self-report data at baseline (for socio-demographic factors), their medical chart review (for clinical factors), or at post-intervention (for their thoughts and preferences on partner participation).

Table 1. Recruitment Totals

Number of subjects per year projected at FCCC	Total number of subjects at FCCC	Number of subjects nationally or internationally (if applicable	Number of subjects at collaborating institutions (if applicable)
Up to: 42	Up to: 42	N/A	N/A

4.2 Recruitment and Reimbursement

Patients. In all, between 30 and 36 patients with gynecologic cancer will participate. Using methods we have employed in previous studies, potentially eligible patients will be identified from consented provider's clinic schedules. This pre-identification process involves pre-screening of patients using their medical records on major characteristics (e.g., length of time since treatment, ECOG score) to reduce unnecessary burden of contacting patients who will not screen in or who may be ill. The research assistant will ask the providers' permission to approach patients identified as medically eligible. If the provider approves, a letter will be sent to a candidate summarizing the research study from the patient's provider including ways the patient can contact the study team to indicate that she is not interested in pursuing the study further. This will be in the form of informational letters or emails, and patients will be called by a member of the study staff for screening. Subjects will receive $20 in compensation for each of the three study assessments. Compensation will be given in the form of gift cards.

Clinicians. Clinicians have been identified from the FCCC gynecologic cancer clinical team. We will enroll between 3-6 FCCC gynecologic cancer clinicians (gynecologic/radiation oncology). Clinicians will be

approached to participate in the study via clinical meetings either in-person or virtually, or through direct contact with Dr. Chu (Co-I), Dr. Reese (PI), or another study team member. Interested clinicians will be sent a link to online consent forms for self-enrollment. Clinicians will be compensated a total of $20 for participating, to complete a brief socio-demographic study survey, and to review the materials we are providing them about menopausal and sexual health concerns after gynecologic cancer. Compensation will be in the form of gift cards.

4.3 Inclusion and Exclusion Criteria

4.3.1. Inclusion and Exclusion Criteria for Patients

Table 2. Eligibility Criteria
Inclusion Criteria
• Female • Age ≥ 18 years • Diagnosis of any stage (I-IV) gynecologic cancer (uterine, ovarian, cervical, vaginal/vulvar, fallopian tube, peritoneal) • Receiving any treatment for gynecologic cancer or have completed acute treatment < 10 years ago • Attending clinic visits in the course of follow-up care (i.e., not an initial consult visit)
Exclusion Criteria
• Not able to speak English • Eastern Cooperative Oncology Group (ECOG)[82] Performance score > 2 • 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.

Our decision to include women with any gynecologic cancer in as opposed to restricting it to women with a cancer of a specific tumor site is guided by findings from prior studies demonstrating similar types of sexual concerns and lack of communication among women in these groups, and is informed by the design of numerous research studies in this area.[6,12,15,28] We choose to include women across a range of stages of disease, those who are in active treatment as well as who have completed treatment, and who are either partnered or unpartnered because women across all of these categories report sexual concerns and are in need of relevant interventions, are similarly likely to report low rates of sexual health communication,[23,24,81] and are willing to participate in such trials.[30] Although we anticipate that women with sexual problems will self-select into the study,[83] as in our previous trial of STC, we do not limit participation by the presence/severity of sexual problems because women could have reason to discuss sexual concerns with their clinician other than for seeking management of sexual difficulties (e.g., to inquire about the safety of sexual activity while undergoing chemotherapy).[84] However, we will collect information to examine this. During screening, women will be assessed for access to an electronic device (e.g., smartphone, tablet, computer); women assigned to STC without such access will be able to use a study laptop to watch the video.

Because gynecologic cancer affects individuals who are biologically female, we do not include biological males in the current study. For simplicity, the term "women with gynecologic cancer" is used in describing the study population. However, we will assess self-identified gender, and will not exclude individuals who identify as male while being treated for a gynecologic cancer (i.e., as in the case of trans men, who may identify as men yet can still be diagnosed with a disease of the female genital tract if these organs are intact). Considering that communication of sexual health can be especially fraught for individuals who are of a sexual or gender minority,[85-87] including such individuals in our study could help us determine whether the STC intervention is generalizable to this underserved population.

4.3.2 Inclusion and Exclusion Criteria for Clinicians

Clinician participants will be gynecologic oncology clinicians or radiation oncologists treating gynecologic cancer patients (physicians, advanced practice clinicians). They will be identified through direct contact by Dr. Chu (Co-I) or by the PI (Reese), or through staff or clinical meetings.

4.4 Screening

Patients. Patients who do not contact the study team to opt out after receiving the recruitment letter will be called by the research assistant to conduct a telephone screening or may be approached in person (i.e., in the FCCC clinic), who will review the study procedures, risks, benefits, and emphasize to patients that their decision to participate will not affect their care. Screening will assess accessibility of computer/devices, and will include a brief assessment of health-related quality of life (e.g., level of sexual concerns, pain, fatigue), and offer a detailed discussion of the study procedures. Recruitment tracking will be done using a combination of password-protected Excel files and REDCap forms. For women who opt out prior to completing screening (e.g., leave us a voicemail saying they do not want to enroll, or refuse over the phone before screening is undertaken), we will collect and retain minimal information (i.e., name, study status) that will allow us to refrain from contacting them again with regard to the study and thus respecting their wishes. Minimal information related to sexual dysfunction issues will be retained for possible grant submission. This information may guide the study design in the future. This information may reveal that patients without any symptoms are less likely to agree to participate. This is considered preparatory to research and will not be used for any purpose other than to guide a future proposal.

Clinicians. All clinicians will be identified in advance as appropriate for the study, negating the need for formal screening procedures.

5.0 Consent Process

For clinicians, consent forms will be presented at that time of contact about the study; Informed consent documents will be presented via paper or web (i.e., REDCap) consents according to the clinicians' preferences.

We have utilized similar online consent processes in multiple patient and provider studies. For patients, consent will occur primarily using a subject specific REDCap form, which will be obtained prior to patients' completion of baseline surveys, which are also online.

For patients who are unable to complete online consents, they will be given the option of signing paper consents either in person or via mail.

All participants will be given the opportunity to ask questions about the study and their involvement prior to consent, and all candidates will be ensured that their participation is voluntary and will not affect their care (if patients) or employment (if providers) at Fox Chase. Only English speakers will be enrolled, so there will not be any consent forms in other languages. No children or minors will be enrolled.

6.0 Measures and Self-Report Data Collection

6.1. Clinician Measures. Clinician self-report data include socio-demographic and clinical self-report items (e.g., length of time in practice, clinical role) and are collected at the time of consent.

6.2. Patient Measures. Patients will complete self-report surveys immediately after enrolling (baseline; T1), at an in-person clinic encounter with their gynecologic cancer clinician several weeks after receiving the intervention materials (post-intervention; T2), and at 2-month follow-up (T3). Self-report data collection will generally be completed using REDCap, a secure, HIPAA-compliant web-based application used successfully in multiple trials in our lab, with paper-and-pencil versions available for those who lack computer access. T2 surveys, which are completed in-clinic immediately following the clinic encounter, will be paper-and-pencil. For patients who are unable to stay in-person to complete their paper survey, online versions of the form will be sent via email to the patient for completion using a link to the online survey with instructions for the patient to complete the survey as soon as possible. Medical data will be gathered through chart review by a qualified member of the research team.

Aim 1. Aim 1 measures include those pertaining to the feasibility and acceptability of the STC intervention in women with gynecologic cancer.

Feasibility will be measured through measures of participant enrollment, defined as the percent of eligible candidates approached who enroll, retention to study completion, defined as completion of all study surveys, and rates of intervention completion, defined by self-report responses on the program evaluation.

Acceptability of the STC intervention will be measured through self-report program evaluation survey administered at post-intervention (after clinic encounter). The main items considered outcomes for this aim are: intervention satisfaction, informativeness, helpfulness, relevance, ease of participation, approval of the format, likelihood of recommending to others, and perceived importance of the program for people with gynecologic cancer. Other items in the program evaluation will assess other aspects of the intervention and may include open-ended items to gather further information that could be useful in improving the intervention content for the larger trial.

Aim 2. Aim 2 measures include self-report outcome measures that will help assess preliminary effects of the STC intervention on patient-clinician communication (beliefs about sexual health, communication behaviors), and on patients' sexual and psychological health outcomes, as shown in Table 3, as well as standard socio-demographic and clinical data collected at baseline through self-report or medical chart review. Self-report surveys will be administered at three time points: Baseline, occurring at the time of consent; Post-intervention (T2), occurring immediately following the clinic encounter; and 2-month

Follow-Up (T3), occurring 2-months after the clinic encounter. Self-report outcome surveys carry an estimated response burden of no more than 30 minutes. Measures of covariates and other study surveys are estimated to take < 10 minutes. **Table 3 below** shows self-report measures used to assess outcomes and a schedule of assessment time points.

Patient-Clinician Communication. Self-Efficacy for Communicating about Sexual Health. Two items assess patients' self-efficacy (confidence) for communicating with their gynecologic cancer clinician about sexual health concerns in terms of either talking (item 1) or asking (item 2) about sexual health. Response options use an 11-point scale (0=not at all confident to 10=extremely confident). Mean scores will be used. Self-efficacy items were developed according to social cognitive theory guidelines[59,88] with input from a trans-disciplinary team, were used successfully in similar studies,[89,90] and had excellent reliability (Cronbach's alpha ≥ .97).[91] Patients' Communication Behaviors. Patients' clinical communication about sexual health will be assessed via self-report measure completed immediately following the patient's T2 clinic encounter, and will be assessed as the proportion of clinic encounters in which the patient reports (1) discussing any sexual concerns with her clinician, (2) raising the topic of sexual health, and (3) asking a question pertaining to sexual health. Analyses of data from our previous trial of the STC intervention in women with breast cancer showed a high kappa coefficient between dialogue coded for discussions of sexual concerns and patients' self-report of discussing a sexual health topic (kappa =.71), suggesting that using self-report to collect the communication data is appropriate. Further, in our prior work, we have found that when sexual health concerns are salient for patients, as they will likely be for most participants, patients tend to be more accurate in their self-reports of sexual health communication during a clinic encounter.[92] As in our previous work,[30,36] the self-report assessment about sexual health will assess whether following topics are discussed, whether the patient raised the topic, and whether the patient asked about any of these topics: sexual activity, function (desire, arousal, orgasm, pain/discomfort), intimate relationships, general sexual concerns, or body image.

Sexual and Psychological Health Outcomes. Sexual activity will be assessed using the PROMIS sexual activity screener item, obtained from the PROMIS SexFS Brief Profile Version 2.0,[91,93,94] which has significant data supporting its validity in women with cancer. This screener assesses any sexual activity (partnered or unpartnered; examples are "masturbation, oral sex, and intercourse") within the past 30 days. Sexual function will be assessed using the 19-item Female Sexual Function Index (FSFI).[95] The FSFI is a widely used comprehensive sexual function measure with established validity in women with cancer,[96-98] which assesses biological, psychological, and social dimensions of women's sexual experiences including desire, arousal, pain, and satisfaction with sexual activity.[76,99,100] Total scores, reflecting women's overall sexual function, capture increases in response to participation in behavioral (non-medical) sexual function intervention trials in women with cancer[76,101] and will be used. Psychological distress is measured by the Hospital Anxiety and Depression Scale anxiety (HADS-A) and depressive symptoms (HADS-D) subscales.[102] Both subscales have had good reliability in prior studies (Cronbach's alpha=.86 and .83, respectively).

Exploratory Aim and Other Measures. The exploratory aim assesses any associations between patients' partnered status or initial sexual concerns score and feasibility, acceptability, and preliminary effects of the STC intervention, Socio-demographic characteristics, such as age, race/ethnicity, sexual orientation, education, socio-economic status, and partnered status will be assessed using the baseline (T1) survey. Patients' sexual concerns will be assessed using a standard item from the Patient Care Monitor, which will be assessed during screening, along with other PCM items (e.g., pain, fatigue, vaginal dryness). These items are assessed using a 0-10 scale and have proven valid and informative in our prior research.[36,92] Clinical variables including stage of disease, tumor site, and dates and types of surgeries and medical treatments will be obtained using medical records. In addition, we will also assess patients' use of sexual

aids (e.g., vaginal health aids such as lubricant or moisturizer) using a validated item from the PROMIS SexFS, as an exploratory measure that could help us determine whether assessing this in the larger trial makes sense. Ultimately, if patients' communication about sexual health is successful, they may employ sexual aids and we want to capture this. Body Compassion. We will assess body compassion, a concept denoting acceptance and compassion toward the physical body, using five items comprising the Acceptance Subscale of the Body Compassion Scale,[34] at baseline. There is growing research suggesting that body image concerns including body compassion are predictors of psychosocial health outcomes for women with gynecologic cancer.[12] Therefore, we will include this measure at baseline to obtain exploratory data that we may use to generate hypotheses for future studies. Medical comorbidity for patients will be obtained by the Self-Administered Comorbidity Questionnaire (SCQ)[103]. In addition to these measures, we will obtain information from patients at the time of screening on health concerns, including sexual concerns, pain, and fatigue, using validated items from the Patient Care Monitor. These items are scored using a 0-10 scale and we have found them to be highly valid in our prior research.

Table 3. Patient Aim 2 Study Self-Report Outcome Measures

Measure	Baseline	Post-Intervention	2-Month Follow-up
Patient-Clinician Communication (Primary)			
Self-efficacy (Beliefs)[88]	X	X	X
Communication Behaviors (Discuss, Raise Topic, Ask a Question)[92]	-	X	-
Patient Sexual and Psychological Health Outcomes (Secondary)			
Sexual Activity (PROMIS-SexFS Sexual Activity Screener)[91,93,94]	X	-	X
Female Sexual Function Index (FSFI)[95]	X	-	X
HADS-Anxiety (HADS-A)[102]	X	-	X
HADS-Depression (HADS-D)[102]	X	-	X
Other Measures (Exploratory)			
Socio-Demographics	X	-	-
Health-Related Quality of Life (HRQOL)	X	X	-
Sexual Aids (PROMIS SexFS)[93]	X	-	X
Body Compassion Scale – Acceptance Subscale[34]	X	-	-
Self-Administered Comorbidity Questionnaire (SCQ)	X	-	-
Program Evaluation	-	X	-

7.0 Randomization

Randomization will occur once the patient has consented and completed the baseline (T1) survey. Using a similar approach as was used successfully in our prior breast cancer trial, patients will be randomized with an allocation ratio of 2:1 to either the STC intervention (video, workbook, and resource guide) or control condition (resource guide only). The statistician (Dr. Handorf) will generate the randomization sequences using an automated randomization procedure in REDCap that limits prediction of allocation and protects masking of allocations. The automated randomization function in REDCap will inform the Research Lab Manager of the patient's assigned treatment condition. Randomization in blocks of six will guarantee that, after every six assignments, the study arms will have equal numbers.

8.0 Intervention Conditions

8.1. Starting the Conversation. The STC intervention consists of a 25-minute video accessible via smartphone, computer or tablet, and an accompanying 5-page workbook providing information and targeted skills training for communicating with providers about sexual concerns. In addition, women will receive a 2-page resource guide consisting of information about institutional and external resources on sexual and menopausal health related to gynecologic cancer and its treatment.[30] The video includes a slideshow with narration and will be made available through a link sent to participants via email; the workbook in in paper format and will be sent via mail. All participants will be sent the resource guide several weeks prior to an upcoming scheduled clinic visit with instructions to read it prior to their visit. Women in the STC intervention arm will also be sent a link via email to the video with instructions to watch the video and complete the exercises in the accompanying workbook prior to their upcoming visit. Participants in both conditions will receive a reminder call close to their scheduled visit, and those who have not reviewed materials close to their visit will be offered the opportunity to come early to their visit and view the materials using a study tablet immediately prior to their clinic encounter in a private space.

STC intervention content was initially developed based on formative qualitative work with breast cancer patients and clinicians on knowledge and skills gaps and intervention preferences[84] and by principles of social cognitive theory,[59] which emphasize building self-efficacy through learning skills for effectively discussing sexual health concerns. Menopausal issues were also included because the treatments commonly given to women with hormonal-dependent breast cancer eliminate estrogen (e.g., aromatase inhibitors, chemotherapy, ovarian suppression) and therefore cause both distressing sexual and menopausal symptoms.[104-107] To maintain consistency with the initially tested intervention while enhancing relevance for gynecologic cancer, we include menopausal issues but focus on genito-urinary symptoms of menopause (e.g., vaginal symptoms, urinary symptoms), since they tend to be highly associated with women's sexual function difficulties.[4,39]

8.2. Control. Women in the control condition will receive the Resource Guide[30] only. The guide will be sent via email to facilitate easy use of webpages by clicking directly on listed links.

9.0 Risks to Participants

This is a behavioral study with few risks. The major risks for study subjects are: (1) discomfort at answering study questions on surveys, or during discussions with clinicians that occur during the trial, although women are free to choose how and what they say during their visit with their clinician to participate and are not required to change anything about their communication, and (2) loss of privacy or confidentiality. Due to the protections we will have in place, we believe these risks to be minimal. Patients will be informed that they do not have to answer any survey items that cause distress or discomfort, and that they are not required to discuss any topics related to sexual health with their clinicians if they do not wish.

10.0 Potential Benefits to Participants

We hope that participants will receive some benefit through participating in the study. However, they may receive no benefit. Patients in both the STC condition or the control condition will receive a handout with reputable resources and evidence-based information about effects of gynecologic cancer on sexual and menopausal health, and they may find this information useful in addressing concerns or in

suggesting resources (e.g., websites) that they could turn to for further information. Patients assigned to the STC intervention may gain skills related to clinical communication about sexual health, which may have a beneficial effect on patient-provider interactions or on aspects of their health, including their sexual health or function, but this cannot be guaranteed. Findings from this study may inform future research on patient-provider communication and sexuality in gynecologic cancer as well as guide the development of interventions to improve the quality of care for patients with gynecologic cancer and potentially other types of cancer or medical conditions. The minimal risks to subjects are reasonable in relation to potential benefit in improving the care of patients with gynecologic cancer.

11.0 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. In order to minimize the risks associated with loss of confidentiality, all patient data will be kept confidential and secure and will be de-identified for analytic purposes. All computers with patient or provider data will be password protected with access restricted to study investigators, and all paper data forms will be kept in locked cabinets. Each participant will have an identifying number that links to his/her name. Access to the linkage list will be limited to study team members and kept in a secure file. A second log will be used to track the number of patients invited to participate, the number who agreed, and the number who refused. This second log will have no personal identifying information, only the patient study number (for patients), the decision on whether to participate, and the reason for refusal, if any. We are concerned with ensuring that our questions about sexuality are handled in a sensitive manner and will assure patients that participation in the research study will not affect their clinical care. In the case that a patient shows increased psychological distress such that continuation in the study is contraindicated, the patient's participation will be terminated and the patient will be given resources including contact information for appropriate mental health professionals.

12.0 Costs to Participants

There are no costs to participants in this study. Self-report data will be obtained at an already scheduled clinic encounter of the patient and parking is free, so there are no costs associated with extra visits or parking.

13.0 Off-Study Criteria

Any participant may leave the study at any time due to distress or other reasons. We do not have a priori reasons for letting participants off the study.

14.0 Drugs and Devices

Not applicable.

15.0 Multi-Site Research Study

Not applicable.

16.0 Statistical Analysis

16.1. Statistical Analyses for Aim 1

16.1.1. Primary and Secondary Outcome Variables

16.1.1.1. Primary outcomes are feasibility and acceptability of the study. Feasibility will be measured through study enrollment, retention (defined as completion of the final survey), and intervention completion (defined as engaging in some or all of the intervention components (i.e., video and workbook; STC arm only)). We will also assess completion of the resource guide across both study conditions, although these data will not be used to determine feasibility. Acceptability is measured using standard self-report items obtained at post-intervention (immediately following clinic encounter); specifically, these items assess intervention satisfaction, informativeness, helpfulness, relevance, ease of participation, liking the format, likelihood of recommending to others, and perceived importance of the program for people with gynecologic cancer.

16.1.2.1. Feasibility. The proportion of study subjects meeting each feasibility measure will be calculated. The following rates will be used as benchmarks for feasibility: Enrollment $\geq$ 60% of eligible candidates; retention $\geq$ 80%; and intervention completion $\geq$ 70%. For enrollment, we will approach patients until clinical communication data are collected on 30 participants, and then stop approaching patients. If we meet our target of 30 enrollments by approaching 50 or fewer patients, the intervention will be declared as feasible.

16.1.2.2. Acceptability. At the individual level, we will determine whether the individual met our acceptability criteria, which we define as endorsing 75% of the 8 acceptability items for the core components of the STC intervention (video and workbook; at least 6 out of 8 items). If 75% of the STC sample (n=15) meets that definition, then we will be able to say that overall the study meets the standard set for acceptability. Other data obtained from the acceptability surveys (e.g., length of time spent using intervention materials, qualitative survey responses) will be analyzed descriptively or using thematic analysis as appropriate. These items will be analyzed across both conditions.

16.1.2.3. Preliminary efficacy. Prior to analyzing outcome data, we examine internal reliability of the outcome measures. In line with recommendations for the analysis of data from pilot studies[108] preliminary outcome data will only be analyzed descriptively, and no formal hypothesis testing will be conducted. Instead we will calculate means and mean differences (from baseline to follow-up assessments) with their respective standard deviations and 95% confidence intervals. Standard effect sizes will also be calculated. These results will inform power calculations for a larger, definitive study.

Analyses for Exploratory Aims. The exploratory aim will characterize the feasibility, acceptability, and preliminary effects of the STC intervention by women's partnered status and level of sexual concerns. We will generate standard descriptive statistics within strata defined by partnered status (partnered vs. not partnered) and level of sexual concerns obtained on the HRQOL scale at baseline. Frequencies, proportions, means, medians, and standard deviations will be calculated and presented. In addition, we will conduct exploratory hypothesis-generating analyses on the novel measure of body compassion, which is assessed only at baseline. For the body compassion data (obtained at baseline only), similar descriptive statistics will first be conducted, as well as exploratory correlational analyses between the body compassion scale and study outcomes, and socio-demographic/clinical correlates or Chi-square for categorical factors.

16.1.2 Sample Size

This study will enroll a total of 30-36 patients, of which 20-24 will be assigned to the intervention and 10-12 assigned to control. The objective of this study is to pilot test the newly adapted STC intervention for women with gynecologic cancer and to allow us to calculate effect sizes, if appropriate, that will inform a larger R01 trial that is expected to follow from this study. We selected 30 participants to participate in this trial because it is a large enough sample to provide ample pilot data while maintaining adequate feasibility in the time allotted. The target sample size is similar to those used in successful prior pilot trials used by the study team.[109] Further, we have chosen a 2:1 allocation to the STC condition, which allows us to gather greater information from participants in this condition, our primary interest, relative to the control condition. The operating characteristics of the feasibility and acceptability rules for this pilot study are given in Table 4. Although we may over-recruit to ensure adequate communication data, feasibility and acceptability rules (see Table 4) will be conducted using the first 30 participants. Probabilities were calculated using the negative binomial distribution for enrollment, and using the binomial distribution for all other feasibility and acceptability benchmarks.

Table 4: Operating characteristics of feasibility and acceptability decision rules

Criteria	Decision rule	Favorable condition	Unfavorable condition	Probability of declaring success if favorable	Probability of declaring success if unfavorable
Enrollment	≥ 60% enrolled (30 accrued with ≤50 approached)	75%	45%	99%	2%
Retention	≥ 80% enrolled (≥ 24/30 enrolled)	90%	65%	97%	6%
Completion	≥70% complete (≥14/20 on STC arm)	80%	50%	91%	6%
Acceptability	≥75% endorse at least 6/8 items (≥15/20 on STC arm)	85%	55%	93%	6%

17.0 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 team member will report any adverse events he or she observes to Dr. Reese immediately. The study consent forms have the contact information for the study PI and the Institutional Review Board (IRB), and patients may contact her or the IRB at any time. The research team will keep a log tracking the number, nature, and frequency of adverse events that occur in both recruiting sites and overall. Because of the nature of the research as involving procedures without significant risk (e.g., surveys; online video intervention) there are unlikely to be any related adverse events. Given the minimal risk of this study, it is determined that a Data and Safety Monitoring Board is not necessary for the proposed study.

18.0 Adverse Events

Because of the nature of the research as involving procedures without significant risk (e.g., surveys; brief communication skills training program) 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. 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.

19.0 Quality Assurance Procedures and Participant Confidentiality

We have designed standardized procedures for every aspect of study administration, from the candidate screening process to administration of the study conditions. Second, all outcome measures have demonstrated excellent psychometric properties and have prior research supporting their appropriateness in the study population and sensitivity to interventions. Third, REDCap, a secure web-based application, will be used for data collection and for randomization, with an automated procedure that limits prediction of allocation and protects masking of allocations. Paper versions of surveys (e.g., post-intervention surveys collected in clinic) will be entered into REDCap by study staff, and the paper versions of the surveys will be locked in a file cabinet containing no identifying information (e.g., surveys are labeled with a random study ID). Only study staff will have access to the REDCap database and the paper versions of the surveys. All files related to study participation (e.g., tracking files) will be kept on Dr. Reese's drive on the Fox Chase network and will be password protected. Finally, to facilitate unbiased data collection and analysis the following steps are taken: 1) the data analyst will conduct outcome data analyses on data in which study condition is masked; 2) outcome data collection is completed in an automated fashion using REDCap, minimizing the need for contact with participants to collect study data. On an annual basis, adverse events will be reviewed across study conditions. During the annual review of adverse events, the presence of significant between-group differences could potentially warrant unmasking of the study conditions by the study biostatistician.

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.

20.0 Participant Informed Consent

See separate Informed Consent document

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22.0 Appendices

- Surveys or Data Collection Tools
  - Self-Report Materials
  - Medical Records Data Collection Form
- Recruitment Materials
  - Recruitment letter/email
  - Recruitment script
  - Recruitment flyer/brochure