Open Pilot Trial of a Novel Mind-Body Sexual Well-Being Intervention for Female GI Cancer Survivors (24-009)

NCT06331403

Study Protocol and Statistical Analysis Plan

Updated July 8, 2024

PROTOCOL TITLE:

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1.0 Objectives*

The primary objective of this protocol is to **conduct an open pilot to elicit initial quantitative and qualitative feedback on the intervention that we are developing.** To do so, we will deliver our novel intervention to 2 consecutive groups of female colorectal and anal cancer survivors ($n \sim 10$ per group, total $N \sim 20$). Participants will provide feedback regarding intervention acceptability, feasibility, and perceived benefit.

To inform plans for ongoing program refinement, we will also elicit specific feedback regarding study assessment tools, recruitment procedures, and group composition.

In future, larger-scale, work, we intend to conduct a larger randomized pilot trial to assess intervention acceptability, feasibility, as well as preliminary efficacy on essential indices of sexual well-being.

2.0 Background*

Many female colorectal and anal cancer survivors experience poor sexual quality of life. Over 700,000 American women are living with gastrointestinal (GI) malignancies, including colorectal or anal cancer.[1-3] Mortality for these gastrointestinal cancers is also decreasing, suggesting that many women will live as cancer survivors for many years.[1] As a result of GI cancer treatments such as surgery, radiation, and chemotherapy, many survivors experience serious long-term side effects such as infertility, diarrhea, incontinence, sexual dysfunction, and in many cases, the need for a temporary or permanent stoma and colostomy bag.[4, 5] Specific sexual effects commonly experienced by female survivors include vaginal dryness and dyspareunia (reported by roughly 30% of colorectal cancer survivors).[4, 6] Further, these physical changes yield indirect effects on psychological and relational factors as body image, libido, and ability to enjoy intimacy.[6, 7]

Unfortunately, women's sexual well-being is often neglected in survivorship care.[8-10] Nurse-delivered patient education about vaginal dilators, moisturizers, and lubricants demonstrates initial promise for vaginal stenosis among colorectal and anal cancer survivors,[11, 12] but does not address other aspects of sexual well-being, such as body image, reduction of physiological stress symptoms, and communication. Thus, there is a need for a novel mind-body intervention to target interacting physiological, emotional, cognitive, and relational contributors to women's sexual well-being in colorectal and anal cancer survivorship.

Based on the established scientific literature as well as our own preliminary qualitative research, we anticipate that our novel group-based intervention holds promise for women who experience these common and distressing, yet under-addressed symptoms and

propose to conduct an initial open pilot trial of our intervention to elicit feedback for future refinement efforts.

3.0 Inclusion and Exclusion Criteria*

3.1 Screening

The study team will utilize the EHR (Epic) to screen potentially eligible survivors, as we have done for existing clinical and research programs. A clinical research coordinator (CRC) will review survivors' EHR to ensure they meet the study eligibility criteria, with consultation from a study investigator or medical provider as necessary.

3.2 Inclusion/Exclusion

Inclusion Criteria

1. Female sex
2. English-speaking
3. Aged 18 or older
4. Receive any cancer care at MGH-CC sites (Boston, Waltham, Danvers, Newton Wellesley Hospital)
5. Completed initial active treatment (i.e., surgery, radiation, chemotherapy) for colorectal or anal cancer approximately 3 months or more prior to enrollment or diagnosed longer than 3 months ago if in metastatic cancer treatment.

Consistent with the National Comprehensive Cancer Network survivorship guidelines[13] and screening procedures previously implemented by our team (DF-HCC Protocol #22-586), we will include female survivors of all ages endorsing sexual health concerns that negatively impact quality of life. Women on long-term endocrine therapies will not be excluded.

Given the scientific aims of this study (i.e., addressing women's sexual well-being), we are including only participants who identify their sex at birth as female and/or current gender identity as woman. Individuals who identify with all races and ethnic groups are eligible for this trial.

Exclusion Criteria

1. Active psychiatric or cognitive comorbidity that prohibits the capacity to provide informed consent as determined by the study PI, a licensed psychologist, in collaboration with the patient's medical team
2. Adults unable to complete study procedures in English.
3. Adults who participated in the qualitative phase of this trial are not eligible for the pilot groups.

We are unfortunately unable to include individuals who are not fluent in English for this small open pilot trial, as the intervention content is currently only available in English (which is also the primary language in which our small study team is qualified to provide clinical services). We intend to prioritize broader inclusion of individuals who speak other languages in future larger-scale work.

*1.1 **Special Populations:***

We will not enroll the following special populations: adults unable to consent, individuals who are not yet adults (i.e., < age 18), pregnant women, and prisoners.

4.0 Study-Wide Number of Subjects*

We will enroll up to 20 individuals, all recruited from MGH main campus and satellite sites, in this study.

5.0 Study-Wide Recruitment Methods*

N/A – this is a single site study.

6.0 Multi-Site Research*

N/A – this is a single site study.

7.0 Study Timelines*

We anticipate that participants will have approximately 4 months of active involvement. During this time, they will complete 6 approximately 1.5 hour approximately weekly group sessions as well as provide survey data and exit interviews.

8.0 Study Endpoints*

Primary aim:

We will conduct a single-arm feasibility trial to examine the feasibility and acceptability of delivering a group-based mind-body sexual well-being intervention delivered via videoconference technology for up to 20 women who have completed treatment for colorectal or anal cancer. Specifically, we will assess whether a virtually-delivered, 6-week sexual well-being group intervention for female colorectal and anal cancer survivors is: **a) Feasible** (assessed by evaluating recruitment/enrollment rates and adherence to sessions) and **b) Well-accepted** (defined by program satisfaction, ease and utility). Given the preliminary, open pilot nature of this protocol, we will not set *a priori* criteria to establish feasibility and efficacy but will rather interpret each of these metrices holistically. Qualitative feedback gathered in post-intervention exit interviews will also add to our understanding of feasibility and acceptability (see Table 1 below).

Secondary aim:

We will explore the preliminary effects of the intervention on psychosocial measures of satisfaction with sex life and impact of functional limitations, coping abilities, acceptance of body image changes, loneliness, and anticipated stigma (see Table 1). As noted above, we will not set *a priori* criteria to establish preliminary efficacy, nor will we consider statistical significance as an indicator of study efficacy. Instead, we will consider pre-post intervention effect sizes to consider the need for refinement of study procedures/measurement in a future efficacy trial.

We will complete the open pilot trial after completing 2 group intervention cohorts with approximately 10 participants per group. Primary outcomes of interest are listed below:

Table 1. Measures for Open Pilot Data Collection

Construct	**Measurement**	**Data Source**
Feasibility		
Recruitment	Percent screened of eligible patients identified	Clinic logs (Epic) and recruitment tracking
Screening/Eligibility	Percent eligible of individuals screened	Recruitment tracking log
Enrollment	Percent randomized of those eligible	Recruitment tracking & randomization log
Engagement	(*) Percent completed 66% (4/6 sessions) of those enrolled	Session attendance logs
Data Collection	Percent with complete pre-post and post-session data	REDCap tracker
Acceptability		
Intervention	(*) Overall comfort with intervention; satisfaction with virtual format; satisfaction with clinician; likelihood of recommending to others (1-5 Likert scales). *Content likes, dislikes, suggestions for improvement.*	Self-report in REDCap (1 item each); *Qualitative exit interviews*
Assessments	Ease of survey completion (1-5 Likert scale). *Experience of completing surveys & suggestions for improvement.*	Self-report in REDCap (1 item); *Qualitative exit interviews*
Sociodemographic and Illness Characteristics (measured at baseline)		

Sociodemographic background	1. Cancer type(s); 2. Time since diagnosis; 3. Cancer staging; 4. Other cancer types; 5. Past treatment types; 5. Time since end of treatment (if applicable); 6. Ongoing or future cancer therapies	Self-report in REDCap (7 items)
Relevant illness information	1. Sex assigned at birth; 2. Current gender identity; 3. Age in years; 4. Race; 5. Hispanic ethnicity; 6. Current relationship status; 7. Sexual orientation	Self-report in REDCap (7 items)
Exploratory Psychosocial Outcomes (all measured at baseline and post-intervention)		
Use of sexual health resources	Single item questions querying use (ever, and # of visits) of: 1) MGH-CC Sexual Health Clinic; 2) MGH-CC Fertility Center; 3) mental health services focused on sexual health and cancer; 4) pelvic PT; 5) sexual well-being discussion with member of main treatment team; 6) sexual well-being discussion with other professional (please specify); 7) Online or written resource for sexual well-being and cancer (please specify); 8) Open-ended description of current concerns	Self-report in REDCap (8 items)
Positive Satisfaction with Sexuality	(^) Sexual Satisfaction Scale for Women – Contentment subscale[14]	Self-report in REDCap (6 items)
Impact of Functional Limitations to Sexuality	NIH PROMIS SexFS – Bother Regarding Sexual Function (Female) subscale[15, 16]	Self-report in REDCap (9 items)
Coping Abilities	Measure of Current Status- Form A (MOCS-A), relaxation and assertive social support-seeking subscales[17]	Self-report in REDCap (5 items)
Loneliness	NIH Toolbox Adult Social Relationship Scales- Loneliness subscale[18]	Self-report in REDCap (5 items)

Cognitive-Behavioral Acceptance of Body Changes	Modified FACT/McGill Body Image Scale (FACT-MBIS)- Self-Image subscale[19]	Self-report in REDCap (11 items)
Anticipated Stigma	Modified chronic Illness Anticipated Stigma Scale-Healthcare workers subscale[20]	4 items - REDCap
Self-efficacy regarding sexual well-being	Single item-questions created for this study regarding understanding of: 1) cancer impact on sexual health; 2) communication strategies for sexual well-being; 3) use of relaxation strategies for sexual well-being; 4) impact of thoughts and feelings on sexual well-being; 5) how to access appropriate resources for sexual well-being	5 items - REDCap
* Indicates primary measure of acceptability or feasibility; ^ Indicates primary effect size of interest		

9.0 Procedures Involved*

This is an open pilot trial to gather initial data regarding feasibility, acceptability, and perceived impact of a 6-session mind-body group intervention that we are developing to enhance sexual well-being among post-treatment female colorectal and anal cancer survivors. *Results of this open pilot will directly inform refinement of our study protocol, for ongoing testing in a future larger randomized pilot trial.* A brief outline of the content that may be included in this intervention is below:

Table 2. *Overview of Anticipated Intervention Structure*

Topic Discussed	**Sexual Well-Being Target**	**Session Content**
1. Defining Stress and Sexual Sequelae of Treatment	Uncertainty about "normal" changes following treatment; education about stress-sexuality connection	1. Session ground rules and what to expect; 2. Effects of cancer treatment on sexual function; 3. Stress reactivity and relaxation response.
2. Social Factors & Women's Sexual Well-Being in Context	Stigma and shame; difficulties communicating needs to medical providers and partners	1. Social and cultural factors that influence women's sexuality; 2. Skills for assertive communication; 3. Overview of medical resources for sexual health (e.g., dilators, lubricants, moisturizers) and common barriers to use

3. Awareness of Thoughts and Feelings	Unhelpful stress-related thoughts about sexuality that interfere with libido and health behaviors	1. Mindful, nonjudgmental awareness of thoughts and feelings related to sexuality; 2. CBT strategies to challenge unhelpful thoughts; 3. Mindfulness as a resource to cultivate awareness of body sensations
4. Body Image Changes	Body image post-treatment and strategies to manage use of ostomy bag (if applicable)	1. Self-compassion & body acceptance; 2. Barriers to (and facilitators of) health behavior engagement; 3. Introduction of guided imagery to cultivate pleasant experience
5. Meditative Movement	Pain/tightness and changes to physical sensation; reactivity to physical sensation	1. Interoceptive awareness of body sensations; 2. Review of strategies for mindful non-judgment; 3. Gentle yoga/movement as a coping resource; 4) Behavioral activation and planning for pleasant physical sensations
6. Meaning-Making of Change	Personal values and goals for sexuality/intimacy; relapse prevention	1. Personal values and meaning-making of change; 2. Review of goals for the future; 3. Use of art/creativity as a coping resource

We will enroll approximately 10 women per group into 2 groups (total $N \sim 20$), based on logistic considerations and previous success with survivorship groups of a similar size. We will run groups consecutively so that any necessary changes from the first open pilot group may be incorporated and re-examined in the second. Based on participant feedback gathered in our qualitative study, we expect that groups will meet online via Zoom. Groups will be led by study PI **Dr. Finkelstein-Fox**, who has expertise in mind-body targets of illness adjustment, in collaboration with Co-I **Dr. Drapek**, who will lend expertise in medical aspects of sexuality in GI cancer survivorship. We expect that each of the 6 weekly sessions will last for approximately 90 minutes and include content related to mind-body medicine and complementary medical resources (e.g., dilators, lubricants, and moisturizers) relevant to survivors' sexual well-being. The rationale for this treatment structure is based on our current survivorship resiliency groups, other cognitive behavioral sexual health interventions for cancer survivors and an existing brief nursing intervention for sexual health in GI oncology led by Dr. Drapek. During the open pilot, **Dr. Park** will provide clinical supervision of **Drs. Finkelstein-Fox and Drapek** and perform fidelity ratings of audio-recorded intervention sessions using checklists developed for the study. **Drs. Bober and Psaros** will also be available for clinical consultation.

Participants will complete electronic informed consent prior to initiation of study procedures. To inform ongoing intervention refinement, we will ask participants to complete 15-minute survey batteries via REDCap at baseline and after the 6-session program, including assessments of intervention feasibility and acceptability as well as psychosocial outcomes including contentment with sex life, psychosocial impact of functional limitations, coping abilities, acceptance of body image changes, loneliness, and anticipated stigma (see Table 1 above). Measures have been selected for their

demonstrated strong psychometric properties in cancer populations, sensitivity to change, and brevity.

Participants will also be invited to complete a brief qualitative exit interview with a member of our study team, regarding perceived benefit of the intervention as well as and strengths and weaknesses of program content and delivery format to inform ongoing intervention refinement (see script attached to this protocol). Participants will be offered up to $60 for participation in study assessments ($20 each for pre- and post- assessments as well as the qualitative exit interview).

At the end of each session, the interventionist will complete an electronic process form indicating the length, location, and content of the session. We will also tally total number and timing of sessions attended for each participant. Attendance data will be logged in REDCap by a CRC.

10.0 Data and Specimen Banking*

N/A

11.0 Data Management* and Confidentiality

11.1 Data Analysis Plan

Qualitative. Qualitative data coding and storage will be conducted using NVivo and/or coding matrices generated by our study team. We will use an audit trail to track data organization, coder strategy, and methods of discussion/interpretation for transparency and replicability. For the purposes of ongoing intervention refinement, qualitative data from open pilot trial participant exit interviews will be analyzed for themes related to participants' experience in the program, perceived benefit, and suggested areas for improvement (see sample interview items attached to this protocol).

Quantitative. Statistical significance will be considered as two-tailed $p < .05$. To explore feasibility of the adapted intervention, we will use descriptive statistics (i.e., frequency and percentages) to evaluate the proportion of enrolled participants who completed 4/6 intervention sessions (75%). We will consider additional feasibility indices including those listed in Table 1. To establish acceptability, we will examine participant scores on an item querying overall comfort with group intervention. Our criteria for acceptability will require a Mean (or Median, depending on data distribution) score $\geq$ 4 on a 1-5 Likert scale from 1 (not at all) to 5 (extremely). Other secondary criteria for acceptability are listed in Table 1. These data will be interpreted holistically together with qualitative feedback to identify areas for revision.

Effect Sizes (Exploratory). Although the intent of this open pilot trial is *not* to perform a fully-powered hypothesis test,[21] we will conduct exploratory analyses of strength of change (i.e., effect sizes) in our primary outcome (Positive Satisfaction with Sexuality; see Table 1). We will consider clinical improvements using within-person analysis of change from pre- (T0) to post-intervention (T1). Depending on model fit, mixed effect multivariable regression models may adjust for 1) time since end of treatment; 2) illness staging; and 3) age. Mixed effect multivariable models will be tested using the "lme4" package[22] for R which allows for use of all available data.

11.2 Sample size justification

Following guidelines for pilot studies and exploratory mixed methods research, we have based sample size for this small proof-of-concept study (N = 2 groups with $n \sim 10$ patients/group) on pragmatics and previous pilot research by our group[21, 23] suggesting that this sample size will be sufficient to inform initial protocol refinement.

11.3 Data Storage

Participant data will be collected using REDCap and exit interviews saved on an MGB secure study folder. Data collected from participants will be kept confidential and accessible only to trained study staff. Participants will be assigned a study identification number, and all collected data will be stored securely with this identification number in files which do not include patient names or any other identifiable information. A link between names and identification numbers will be stored separately in a password protected file. All electronic data will be stored in password protected computer files. Any data files exported from the database will be de-identified, with only a case number identifying each participant, and no other identifying information.

Dr. Finkelstein-Fox will oversee all aspects of data collection and will develop study specific data management protocol and standard operating procedures for the creation and testing of all study forms, data collection, quality control, and data extraction. She will provide ongoing oversight of data management throughout the study and will be responsible for generating reports and datasets for quality control and data analysis.

We will comply with all requirements for data safety and monitoring, as specified by the IRB. As per Public Law 110-85, this is an applicable trial and will be registered and results reported with ClinicalTrials.gov. Dr. Finkelstein-Fox will be responsible for handling ClinicalTrials.gov requirements for this project. She will work closely with the Partners Human Research Affairs QI Program to register the trial prior to enrolling the first subject. Once a record is established, she will confirm accuracy of record content, resolve problems, and maintain records including content update and modification.

11.4 Quality control of collected data

Dr. Finkelstein-Fox will train the study CRC in administration and data management of participant self-report questionnaires. The CRC will be responsible for conducting initial participant eligibility screening using clinic records in EPIC. The CRC will be closely supervised by Dr. Finkelstein-Fox in consultation with study Co-I Dr. El-Jawahri, who is a board-certified oncologist possessing the necessary expertise to oversee collection of patient clinical characteristics and oncology treatment information.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

N/A – this research involves minimal risk only.

13.0 Withdrawal of Subjects*

Should a participant experience an acute psychiatric or medical emergency that, in the clinical judgment of the study PI (a licensed clinical psychologist) and co-investigators (including licensed clinical psychologists, an oncologist, and an oncology nurse practitioner), makes it inappropriate or unsafe for them to continue participation in study procedures, we may ask them to withdraw from the study. Should this occur, the study investigators will provide referrals to meet their needs more appropriately. Non-clinical study staff will contact licensed clinical psychologists Dr. Finkelstein-Fox or Dr. Park in the case of any safety concerns and will provide appropriate mental health referrals or resources for supportive care at the MGH-CC as needed. If a participant requests withdrawal from the study, we will ask them if they are comfortable sharing the reason for withdrawal to ensure that there are no adverse events to report to the IRB.

In the case that participants elect to withdraw from the study during the interview or group/treatment intervention, they will be invited to complete study surveys. Participants who are withdrawn at the discretion of the PI will be thanked for the participation and invited to complete study surveys as the PI deems necessary.

Participants who provide electronic consent but do not complete study measures and/or withdraw or are removed from the study prior to participating in any intervention group sessions will not be counted towards the accrual goal up to 20 participants. We will keep a detailed log of these instances, as this will inform the feasibility of the study.

All participants will be included in the feasibility assessment. We plan to examine the proportion of patients who are eligible and the proportion who are found to be ineligible due to inability to use the videoconferencing software, physician refusal, and medically or psychiatrically unable to participate. Out of those who are eligible, we will examine the proportion of enrollments, refusals, lost-to-follow up, withdraws, and study completers. We will examine reasons for and rates of ineligibility, as these will inform

the feasibility of the study and of delivering the program virtually. We will also examine the characteristics of non-completers and the reasons for non-completion.

14.0 Risks to Subjects*

The risks involved in the study are minimal and will be clearly delineated on the consent form. It is unlikely that participants will be at any risk for physical harm as a result of study participation. Confidentiality will be detailed on the consent form and discussed in detail so that participants are fully informed of their right to request information and to withdraw from the study at any time without impacting their care. We will also discuss the importance of maintaining confidentiality at the beginning of each intervention group to keep information shared confined to the group. Participants will also be made aware of the limits of confidentiality, including that confidentiality would be broken if participants reported thoughts of harming themselves or others, in order to obtain appropriate care for the participant. Participants may choose not to participate in the study or any of the study procedures without penalty. Those who do agree to participate may withdraw their participation at any time without penalty.

Potential risks to participants are minimal across various study procedures and include the following: Questionnaire batteries. Participants may experience some discomfort answering questions on surveys; however, they may choose not to answer questions that are distressing. Group videoconferencing. Participants may have concerns about the security of videoconferencing and will be informed that the system is HIPPA compliant and sanctioned by MassGeneral Brigham HealthCare to protect privacy. Mind-Body Sexual Well-Being Groups. Participants might find some of the exercises (e.g., meditation/relaxation training, discussing concerns with fellow group participants) to be difficult or uncomfortable at first. These difficulties are typically minimal and temporary and are often a natural and valuable part of the treatment process.

Procedures for Minimizing Risk

All possible measures will be taken to ensure patient comfort and participants will be informed that they could exit the study at any point with no penalty. Lead investigators Dr. Finkelstein-Fox (a licensed clinical psychologists) will be available to intervene during study groups or assessment procedures if needed (due to patient discomfort or to answer specific questions about the study). Participants will be informed that they can choose not to answer any questions that make them feel uncomfortable. Every effort will be made to minimize the study burden. The time commitment will be explained to all participants prior to focus groups and qualitative interviews. All these procedures are consistent with sound research design and do not unnecessarily expose subjects to risk. If a participant expresses distress during the interviews, they will be reassured by the clinician or study staff member conducting the interview that they can stop at any time and that they do not need to continue participating in content or answer interview

questions which they find upsetting. They will also be reminded that study participation is voluntary. If participants remain distressed, they will be offered an opportunity to meet with a psychologist in the Psychiatric Oncology Service at the MGH Cancer Center to help address their distress. If the patient needs further outpatient services for depression, including pharmacotherapy, or is at risk for self-harm requiring hospitalization, study staff will make the necessary referrals for treatment. For example, for patients who are distressed but in no danger to self or others, study staff will refer either to the MGH Oncology Social Work Service or to the MGH Outpatient Psychiatry Department (617-724-5600), including the Cognitive-Behavioral Therapy Program. If suicidality or risk of harm to others is otherwise discovered at any study visit, the participant will be referred to appropriate services. Specifically, in the case that hospitalization is required, study staff will contact and escort the patient to the MGH Acute Psychiatry Service (617-726-2995), with the aid of the MGH Police & Security if necessary (617-726-2121). If a referral for outpatient services is made, or the patient requires escort to the MGH Acute Psychiatry Service, study staff will notify the health care team, including the primary oncologist.

The PI and trained study staff will meet weekly to review study progress, ensure properly implementation of the interview, and review any adverse reactions that occur. The PI and the research assistant will review consents and collected data to ensure proper adherence to study protocol.

15.0 Potential Benefits to Subjects*

We do not know if taking part in this open pilot study will benefit participants. This study may help researchers learn how to help women experiencing changes to sexual well-being following treatment for colorectal and anal cancer in the future. However, the risk from participation in the study is small (and will be minimized by the procedures outlined above), and the overall risk to benefit ratio is favorable.

16.0 Vulnerable Populations*

N/A

17.0 Community-Based Participatory Research*

N/A

18.0 Sharing of Results with Subjects*

Given the nature of the population included in the study, it is not appropriate to proactively contact participants at the conclusion of this study. However, we provide the

research team contact information to each participant and encourage them to contact us if they would like to receive updates and information on the research findings.

19.0 Setting

The study will include cancer survivors treated at the Massachusetts General Hospital. Participants will be approached for participation in-person, phone or email, or via patient gateway. The intervention will be delivered via a virtual-HIPPA-compliant videoconferencing technology, Zoom, that is accessible via smartphone, laptop, tablet, or desktop. All participants will also be invited to complete an exit interview that will be conducted virtually or in person.

20.0 Resources Available

20.1 Study Team Qualifications. Prior to working on any human subject aspects of the study, all study staff will complete the required human subjects training. No identifying information will be kept on any study forms. The study CRC will be responsible for assigning unique study IDs and for maintaining a log that links participant names with their unique study identifier; this log will be password-protected, kept separate from study information and stored in a study network folder which is backed up nightly. All data collected will be stored with this identifier. Electronic data will be kept confidential, stored in secure servers, password-protected and protected by anti-virus software, and accessible only to trained and IRB-approved study staff.

Study staff will also be required to undergo human subjects training prior to engaging in any research activities. The CRC will have regular meetings with the study PI to review accrual, retention, attrition, and data completeness.

20.2 Other Relevant Resources. Drs. Finkelstein-Fox, Park, and El-Jawahri are members of the MGH Cancer Outcomes Research and Education Program (CORE). CORE has extensive experience conducting randomized clinical trials of supportive care interventions in oncology and has the necessary expertise to ensure the success of the proposed project. Drs. Finkelstein-Fox, Park, and El-Jawahri are also members of the MGH Health Promotion and Resiliency Intervention Research Program, which houses expertise and research staff focused on mind-body interventions. We will also have relevant resources from the MGH Behavioral Medicine Program, of which Drs. Finkelstein-Fox, Park, and Psaros are members, and the MGH Cancer Center Sexual Health Clinic, of which Dr. Drapek is the Director.

21.0 Prior Approvals

Funding is provided by the Harvard Osher Center. No additional approvals are required.

22.0 Recruitment Methods

We will recruit participants by reviewing patient clinic records on Epic and conducting proactive outreach, as well as via physician and patient self- referral from the MGH-Cancer Center. Specific recruitment methods are outlined below.

22.1 Eligibility Pre-Screening in Epic. All patients will be pre-screened for eligibility prior to contact using clinic records in Epic (see request for HIPAA Waiver below). Eligible patients will then be contacted by the study team to complete eligibility phone screening (see script attached to this protocol). Eligible and interested patients will then be directed to complete the informed consent process via electronic consent in REDCap (see consent form attached to this protocol).

We are requesting a HIPAA Waiver of Authorization to Review Preparatory to Research from the IRB. We are requesting this Waiver to identify potential patient participants from a minimal chart review. In accordance with the DF/HCC policy, this Waiver: (1) is being sought solely to review Protected Health Information as necessary to prepare a research protocol, (2) will not include removing Protected Health Information from the Covered Entity by the researcher, and (3) is necessary for the research purposes.

Epic Screening and Proactive Outreach. Following Epic screening, we will communicate with a qualified oncology clinician via email, through the electronic health record, or verbally to notify them that the patient is eligible for the study and inquire about any concerns regarding their participation. If the oncology clinicians have objections to the patients' participation in the study, we will document the reason and not approach those individuals. If the oncology clinicians have no objections or does not respond within 5 business days, the CRC will approach the potentially eligible patient to invite them to participate in the study and review the nature of all study procedures. The CRC can approach the survivor in-person during a medical visit or over the telephone/video call to perform initial eligibility screening and begin the informed consent process. Reasons for refusal and ineligibility will be documented.

22.2 Provider Referral and Patient Self-Referral. We have developed a study flyer that clinicians may share with potentially eligible patients to facilitate direct patient outreach. Participants recruited via direct referrals from their providers may either contact study staff directly using the information their provider gave them (see attached flyer), and/or the provider will contact the study team with the patient's information so that the study team may reach out to the patient.

22.3 ONCORE Registration of Eligible Participants. We will register eligible participants in the Clinical Trials Management System (CTMS) Oncore as required by

DF/HCC SOP REGIST-101. Registration must occur prior to the initiation of protocol-specific procedures or assessments. For registration of patients, study staff will complete the DF/HCC protocol-specific eligibility checklist using the eligibility assessment documented in the participant's medical record and/or research chart. Study staff will confirm that the participant meets all inclusion criteria as described in this protocol and the criteria on the eligibility checklist.

22.4 Strategies for Recruitment of Diverse Participants. For this small proof-of-concept open pilot trial, we will make every effort to recruit individuals whose sociodemographic characteristics mirror the characteristics of individuals with colorectal and anal cancer in the general population. Based on our earlier qualitative research project recruiting a similar patient population (DFCI IRB #22-586), we anticipate that efforts to enhance diverse participation may be especially important for non-Hispanic Black individuals and those with lower socioeconomic status. To prioritize inclusion of individuals, we will use strategies previously employed by our group, including outreach to MGH-CC satellite sites and use of inclusive language/images on our study recruitment materials. Sociodemographic inclusion will also be a focus of future larger-scale trials to continue refinement of this work.

22.5 Remuneration. Participants who complete all study procedures may receive up to $60 remuneration via gift cards ($20 for pre-program survey, $20 for post-program survey, $20 for exit interview).

23.0 Local Number of Subjects

We expect to enroll up to 20 participants in the study protocol. Participants will not complete the full signed informed consent (i.e., enrollment) until they have completed an initial eligibility screening and confirmed interest in participating to the study CRC.

24.0 Provisions to Protect the Privacy Interests of Subjects

During the initial informed consent procedure, eligible individuals will be told that participating in the research study is voluntary, and that they are able to withdraw at any point with no penalty or loss of benefits to them. Given the sensitive nature of the study topic, we will also remind participants that they are not required to answer any question that makes them uncomfortable, nor are they required to participate in any study procedure that makes them uncomfortable.

The study will be monitored by the investigative team. As described in section above, to safeguard participant information and confidentiality, all data will be stored in locked office space at MGH as well as in password-protected computer files, accessible only to

trained and IRB-approved study staff. Participants' data will be identified by an ID number only, and a link between names and ID numbers will be kept separately under lock and key or in a separate password protected document accessible only by study staff. Data identified by ID numbers may also be stored in REDCap, a secure, web-based application designed to support data capture for research studies.

Transcripts of all exit interviews will be de-identified, and participants will be directed to avoid using personal identifiers (i.e., birthdays, home address, full names) during the interview, thus maintaining patient anonymity and confidentiality during the interview. Audio- records of these interviews will be uploaded to our study access-restricted drive. Interviews will either transcribed directly by research study staff or be sent securely and transcribed by transcribeme.com.

25.0 Compensation for Research-Related Injury

N/A – this study does not involve more than minimal risk.

26.0 Economic Burden to Subjects

N/A – participants are not expected to incur any costs because of participation in this research.

27.0 Consent Process

27.1 ***Initial Phone Eligibility Screening.*** We request a waiver of signed informed consent for our initial study phone screening process (see phone screen script attached to this protocol). In the attached phone screening document, we ask participants to provide verbal consent for initial phone-screening to confirm study eligibility. If study eligibility is confirmed during phone screening, participants will be invited to provide informed consent for the study (process described below).

27.2 ***Informed Consent for Study Participation (e-consent or signed paper form).*** Participants will be asked during the initial phone screening phase whether they prefer to complete the study consent forms electronically vs. in person. We will also ask participants about their preference for encrypted (our default option) or unencrypted email during this screening call; their preference will be documented and used to inform means of future outreach.

For those who prefer an in-person consent procedure, we will schedule a brief in-person appointment with a member of our research team, who will review the consent form with the participant in detail, answer any questions, sign, and provide a photocopy of the signed consent form to the participant for their records.

For those who prefer an electronic copy of the consent form, we will schedule a brief phone appointment with a member of our research team. Following the MBG RedCap e-consent form template, study staff will fill out the first survey in the template (i.e., date of birth, name, and email of participant). RedCap will automatically email the participant a link to a RedCap survey in which they can read the consent form. To access the form, participants are required to input their birthdate. The consent form will be identical to the paper version (no hyperlinks or additional information available). During the phone appointment, research staff will review the consent form with the participant as is done in the in-person procedure, answering any questions as they arise. While on the phone with our research staff, participants will provide electronic consent in REDCap. Participants will always have the option to end, pause, or review any part of the consent process according to their preference during this phone call with study staff. After the participant has signed the consent form, the consenting study team member will sign the form and download a copy to send to the participant. Any email correspondence containing a signed study consent form will be sent with encrypted email, unless participants directly state a preference for unencrypted email. Our study team will also download and save a signed copy of all e-consent forms to our research files. REDCap automatically captures a timestamp containing time/date of e-consent signature.

28.0 Process to Document Consent in Writing

As described above, the CRC will conduct informed consent procedures with eligible potential participants and obtain electronic consent. Signed copies of the electronic consent form will be saved to the study server and emailed to each study participant for their records. If participants prefer a paper consent form (signed in-person), we will scan and save an electronic copy of the consent form to our server as well as save the original signed copy in a locked file cabinet in the PI’s office.

29.0 Drugs or Devices

N/A

1. National Cancer Institute Survey Epidemiology, & End Results (SEER) Program. Cancer of the colon and rectum - cancer stat facts. 2022 [January 28, 2022]. Available from: https://seer.cancer.gov/statfacts/html/colorect.html.
2. National Cancer Institute Survey Epidemiology, & End Results (SEER) Program. Cancer of the anus, anal canal, and anorectum - cancer stat facts. 2022 [January 28, 2022]. Available from: https://seer.cancer.gov/statfacts/html/anus.html.
3. American Cancer Society. Colorectal cancer facts & figures 2020-2022. Cancer Facts and Statistics. 2022 [January 28, 2022]. Available from: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf.
4. El-Shami K, Oeffinger KC, Erb NL, Willis A, Bretsch JK, Pratt-Chapman ML, Cannady RS, Wong SL, Rose J, Barbour AL, Stein KD, Sharpe KB, Brooks DD, Cowens-Alvarado RL. American Cancer Society Colorectal Cancer Survivorship Care Guidelines. CA Cancer J Clin. 2015;65(6):428-55. Epub 20150908. doi: 10.3322/caac.21286. PubMed PMID: 26348643; PMCID: PMC5385892.
5. Ramirez M, McMullen C, Grant M, Altschuler A, Hornbrook MC, Krouse RS. Figuring out sex in a reconfigured body: experiences of female colorectal cancer survivors with ostomies. Women Health. 2009;49(8):608-24. doi: 10.1080/03630240903496093. PubMed PMID: 20183104; PMCID: PMC2836795.
6. Den Oudsten BL, Traa MJ, Thong MS, Martijn H, De Hingh IH, Bosscha K, van de Poll-Franse LV. Higher prevalence of sexual dysfunction in colon and rectal cancer

survivors compared with the normative population: a population-based study. Eur J Cancer. 2012;48(17):3161-70. Epub 20120517. doi: 10.1016/j.ejca.2012.04.004. PubMed PMID: 22608772.
7. Acquati C, Hendren S, Wittmann D, Reese JB, Karam E, Duby A, Dunn KB, Kayser K. Psychological and sexual distress in rectal cancer patients and partners. Psychooncology. 2022;31(6):920-8. Epub 20220120. doi: 10.1002/pon.5880. PubMed PMID: 35001478.
8. Traa MJ, De Vries J, Roukema JA, Den Oudsten BL. Sexual (dys)function and the quality of sexual life in patients with colorectal cancer: a systematic review. Ann Oncol. 2012;23(1):19-27. Epub 20110420. doi: 10.1093/annonc/mdr133. PubMed PMID: 21508174.
9. Wo JY, Drapek LC, Niemierko A, Silvia B, Noe BN, Russo AL, Miyamoto DT, Hong TS, Efstathiou JA, Zietman AL, Dizon DS. Clinical needs assessment for sexual health among cancer patients receiving pelvic radiation: Implications for development of a radiation oncology sexual health clinic. Pract Radiat Oncol. 2018;8(3):206-12. Epub 20171121. doi: 10.1016/j.prro.2017.11.004. PubMed PMID: 29426693.
10. da Silva GM, Hull T, Roberts PL, Ruiz DE, Wexner SD, Weiss EG, Nogueras JJ, Daniel N, Bast J, Hammel J, Sands D. The effect of colorectal surgery in female sexual function, body image, self-esteem and general health: a prospective study. Ann Surg. 2008;248(2):266-72. doi: 10.1097/SLA.0b013e3181820cf4. PubMed PMID: 18650637.
11. Drapek LC CM, Sheldon LK, Wo, J. A Multimodal Continuity of Care Program to Prevent or Minimize Vaginal Effects of Pelvic Radiation therapy in Women with Lower Gastrointestinal or Gynecologic Cancers. Oncology Nursing Society- Annual Congress; Washington, DC2018.
12. Drapek LC NB, Hong TS, Dizon DS, Wo JY. . Longitudinal Follow-up of Women Receiving Pelvic Radiotherapy for Gynecologic and Lower GI or Gynecologic Cancers. American Society of Therapeutic Radiation Oncology (ASTRO)-Annual Conference; Chicago, IL2019.
13. Denlinger C, Sanft T, Baker K. Survivorship, Version 2.2018, NCCN Clinical Practice Guidelines in Oncology 2018 [cited 16]1216-47].
14. Meston C, Trapnell P. Development and validation of a five-factor sexual satisfaction and distress scale for women: the Sexual Satisfaction Scale for Women (SSS-W). J Sex Med. 2005;2(1):66-81. doi: 10.1111/j.1743-6109.2005.20107.x. PubMed PMID: 16422909; PMCID: PMC2859306.
15. Flynn KE, Lin L, Cyranowski JM, Reeve BB, Reese JB, Jeffery DD, Smith AW, Porter LS, Dombeck CB, Bruner DW, Keefe FJ, Weinfurt KP. Development of the NIH PROMIS (R) Sexual Function and Satisfaction measures in patients with cancer. J Sex Med. 2013;10 Suppl 1:43-52. doi: 10.1111/j.1743-6109.2012.02995.x. PubMed PMID: 23387911; PMCID: PMC3729213.
16. Flynn KE, Reeve BB, Lin L, Cyranowski JM, Bruner DW, Weinfurt KP. Construct validity of the PROMIS(R) sexual function and satisfaction measures in

patients with cancer. Health Qual Life Outcomes. 2013;11:40. Epub 20130311. doi: 10.1186/1477-7525-11-40. PubMed PMID: 23497200; PMCID: PMC3618202.
17. Carver CS. Measure of current status 2006 [November 11, 2021]. Available from: https://local.psy.miami.edu/people/faculty/ccarver/availbale-self-report-instruments/mocs/.
18. Cyranowski JM, Zill N, Bode R, Butt Z, Kelly MA, Pilkonis PA, Salsman JM, Cella D. Assessing social support, companionship, and distress: National Institute of Health (NIH) Toolbox Adult Social Relationship Scales. Health Psychol. 2013;32(3):293-301. doi: 10.1037/a0028586. PubMed PMID: 23437856; PMCID: PMC3759525.
19. Rodriguez AM, Frenkiel S, Desroches J, De Simone A, Chiocchio F, MacDonald C, Black M, Zeitouni A, Hier M, Kost K, Mlynarek A, Bolster-Foucault C, Rosberger Z, Henry M. Development and validation of the McGill body image concerns scale for use in head and neck oncology (MBIS-HNC): A mixed-methods approach. Psychooncology. 2019;28(1):116-21. Epub 20181112. doi: 10.1002/pon.4918. PubMed PMID: 30312500.
20. Earnshaw VA, Quinn DM, Kalichman SC, Park CL. Development and psychometric evaluation of the Chronic Illness Anticipated Stigma Scale. J Behav Med. 2013;36(3):270-82. Epub 20120413. doi: 10.1007/s10865-012-9422-4. PubMed PMID: 22526525; PMCID: PMC4370181.
21. Czajkowski SM, Powell LH, Adler N, Naar-King S, Reynolds KD, Hunter CM, Laraia B, Olster DH, Perna FM, Peterson JC, Epel E, Boyington JE, Charlson ME. From ideas to efficacy: The ORBIT model for developing behavioral treatments for chronic diseases. Health Psychol. 2015;34(10):971-82. Epub 20150202. doi: 10.1037/hea0000161. PubMed PMID: 25642841; PMCID: PMC4522392.
22. Bates D, Mächler M, Bolker B, Walker S. Fitting Linear Mixed-Effects Models Using lme4. Journal of Statistical Software. 2015;67(1):1 - 48. doi: 10.18637/jss.v067.i01.
23. Hall DL, Yeh GY, O'Cleirigh C, Peppercorn J, Wagner LI, Denninger J, Bullock AJ, Mizrach HR, Goshe B, Cheung T, Li R, Markowitz A, Park ER. A Multi-step Approach to Adapting a Mind-Body Resiliency Intervention for Fear of Cancer Recurrence and Uncertainty in Survivorship (IN FOCUS). Glob Adv Health Med. 2022;11:21649561221074690. Epub 20220127. doi: 10.1177/21649561221074690. PubMed PMID: 35237466; PMCID: PMC8883302.