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

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Study Consent Document

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Protocol Title: Open Pilot Trial of a Novel Mind-Body Sexual Well-Being Intervention for Female GI Cancer Survivors

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Main Consent – Open Pilot Trial

INTRODUCTION AND KEY INFORMATION

The following is a short summary of this research study to help you decide whether you would like to be a part of this study. More detailed information is provided later in this form.

For purposes of this research, you will be referred to as a "participant."

1. Why am I being invited to take part in a research study?

You are invited to take part in this research study because you have you have completed initial active treatment for colorectal or anal cancer at the MGH-CC at least three months ago or have been diagnosed with metastatic cancer at least 3 months ago.

2. Why is this research being done?

The main purpose of this study is to identify essential components of an integrative mind-body sexual well-being intervention that we are designing to support the needs of women who have completed colorectal or anal cancer treatment and experience concerns related to changes in sexual well-being and intimacy.

3. Who is supporting this research?

Harvard's Osher Center for integrative Medicine is supporting this research.

4. What does this research study involve and how long will it last?

This research study involves participating in a 6-week-long group program with approximately 3-9 other women who have completed initial active treatment for colorectal and anal cancer. The group will take place over Zoom and last for about 90 minutes per meeting. The group may provide specific information related to female survivors' sexual well-being. You do not have to share any personal information that you are uncomfortable with during these groups.

As part of the research study, you will be asked to complete two 15-30 minute-long surveys (before and after the group program). You will also have the option of completing a brief 30-minute exit interview with a member of the study team to help us improve the program we are developing.

You may be in this research study for up to 6 months, including the time that it takes for you to complete the group program, study surveys, and the optional exit interview.

5. What are the risks to participating in this study?

There are risks to taking part in any research study. We want to make sure you know about a few common risks right now. More information about these risks is provided in "Section C. What are the risks or discomforts of the research study?".

Major known risks to participating in this research study include:

- Disclosure of personal information may result in a loss of privacy
- Possible emotional distress when answering questions or discussing anal or colorectal cancer and sexual health
- There is a small risk of a breach of confidentiality, but we take all available precautions to maintain confidentiality and to minimize this risk.
- The amount of time required to participate in the study intervention (90 minutes per meeting for 6 weeks) and complete study assessments (surveys and an optional exit interview)

6. Will being in this study benefit me in any way?

We do not know if taking part in this study will benefit you. This study may help researchers learn information that could help people in the future.

7. What are my options?

Instead of being in this research study, you have other options which may include the following:

- Decide not to participate in this research study
- Participate in another research study.

All research is voluntary. It is your choice whether you take part in this research or not. If you decide to participate, please sign and date at the end of this form. We will give you a copy and you can refer to this consent form at any time.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions at any time.

A. WHY IS THIS RESEARCH STUDY BEING DONE?

Many women survivors of colorectal and anal cancer experience concerns related to their sexual well-being. Women's sexual health is connected to stress and emotional well-being and is sometimes difficult to treat using medication alone. Because of this, we are designing a psychologically-informed mind-body stress reduction intervention for women to enhance this important part of life during cancer survivorship.

This research study is called a "pilot study," which means that this is the first time investigators are examining an intervention targeted at interacting physiological, emotional, cognitive, and relational contributors to women's sexual well-being in colorectal and anal cancer survivorship. We hope that information gathered in this study will help us to refine the intervention that we are developing, so that we can continue improving it in future research.

It is expected that about 20 people will take part in this pilot research study.

B. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the study intervention:
After completing this consent form, we will ask you to complete a brief (15-30 minute) **survey** including questions related to your health and well-being (including aspects of emotional and sexual health). You do not have to answer any questions that you do not want to.

During the study intervention:

You will be invited to **attend six 90-minute group meetings via Zoom**. Groups will meet approximately once per week. We think that approximately 4-10 female

survivors of colorectal and anal cancer will attend each group, along with approximately two trained group facilitators from our research team. The groups will include content related to cancer survivorship, women's sexual health, and emotional well-being. During these groups, you do not have to share any personal information that you don't want to.

To help us understand how we might need to modify this new group program for the future, we will audio-record all group meetings. This recording will be stored on a secure MGB server accessed only by qualified study team members. Recordings will be permanently erased at the end of the study.

After the study intervention:
After completing the 6-week group intervention, we will invite you to complete a brief (15-30 minute) **survey** including questions related to your health and well-being (including aspects of emotional and sexual health), which will help us understand how the study intervention impacted you. As noted above, you do not have to answer any questions that you do not want to.

We will also invite you to participate in a 30-minute **exit interview** with a member of our team. As described above, these interviews will be audio-recorded to make sure that we do not miss any of the information you share with the interviewer. This recording will be stored on a secure MGB server accessed only by qualified study team members. Recordings will be permanently erased at the end of the study.

C. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study, including the possibility of a breach of confidentiality. However, we will take steps to minimize the risk

Potential risks to participating in this research study include:

- Disclosure of personal information may result in a loss of privacy
- Possible emotional distress when answering questions or discussing anal or colorectal cancer and sexual health
- There is a small risk of a breach of confidentiality, but we take all available precautions to maintain confidentiality and to minimize this risk. In the event of an emergency, confidentiality may be suspended if you are at risk of hurting yourself or someone else. Confidentiality may also be suspended in suspected cases of abuse or neglect of a child, elder, or person with a disability.

During the research study, you will be provided with any new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

D. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH?

You may be taken off the research study for any reason including:

- It is considered to be in your best interest
- The study intervention or procedures are found to be unsafe or ineffective
- There is any problem with following study intervention and procedures
- Your condition worsens
- A decision is made to end the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

You can also choose to stop participating in the research study at any time. Tell the study investigator if you are thinking about stopping or decide to stop. They will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

E. WHAT ARE THE BENEFITS OF THIS RESEARCH STUDY?

Taking part in this research study may or may not benefit you. We hope the information learned from this research study will provide more information about ways to enhance women's sexual well-being in colorectal and anal cancer survivorship.

F. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

As a token of gratitude for your time, you will be offered up to $60 for completed study assessments ($20 each for pre- and post-assessments and the qualitative exit interview).

G. WHAT ARE YOUR COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company. You will not be charged for your participation in the group program that we are testing.

H. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the study investigator or study staff as listed below:

- Lucy Finkelstein-Fox, PhD – Principal Investigator 617- 724-6300 ex. 111-133-0076
- Isabelle Miranda – Clinical Research Coordinator 617-726-6992

24-hour contact: Lucy Finkelstein-Fox, PhD – page at 617-726-2000, beeper # 27257

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

I. RETURN OF RESEARCH RESULTS

Information collected for this research study is only for research and have no clear meaning for your health care. For this reason, the study team will not share the results with you. Importantly, there are no tests involved in this phase of the study.

J. CLINICALTRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

K. FUTURE USE OF DATA AND SPECIMENS

Your personal information collected during this study will not be used for any future research after this study is complete.

L. CONFIDENTIALITY

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

The study team may publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications.

Information about you and your health is personal and private. Generally, it cannot be obtained without your written permission. By signing this form, you are providing that permission and your information may be obtained and used in accordance with this informed consent and as required or allowed by law. This means that researchers may obtain information regarding your past medical history, as well as specimens and samples from previous health care providers such as hospitals and labs.

M. FINANCIAL DISCLOSURES

It is possible that certain researchers on this study may have earned money from, or own some publicly-traded stock in, the company that makes or is developing the study intervention. The amount of money that a researcher may earn and still take part in research is limited by the Harvard Medical School Faculty of Medicine Policy on Conflicts of Interest and Commitment. If you have further questions, please speak with a member of the study team or contact the Dana-Farber Cancer Institute Office of Research Integrity at 617-432-4557 or researchintegrity@dfci.harvard.edu.

N. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug(s) and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, representatives, business partners, and its agent(s): Harvard Osher Center for Integrative Medicine
- Other research doctors and medical centers participating in this research, if applicable

- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the study investigators and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”

O. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

Signature of Participant	Date

To be completed by person obtaining consent:

Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant or legally authorized representative is a non-English speaker who received and signed the translated Short Form in lieu of English consent document, and was provided a copy

☐ *As someone who understands both English and the language used by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.*

Signature of Interpreter: _____

Signature of Witness: _____
Interpreter may also serve as Witness if present

Printed Name of Interpreter: _____

Printed Name of Witness: _____

Date: _____

☐ 1b) Participant or legally authorized representative is a non-English speaker who received and signed a translated consent form in the language they understand, and was provided a copy

☐ 1c) Participant is unable to sign the consent form because:

☐ The participant is unable to read and write.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Interpreter: _____

Signature of Witness: _____
Interpreter may also serve as Witness if present

Printed Name of Interpreter: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

- ☐ 2a) gave permission for the adult participant to participate
- ☐ 2b) did not give permission for the adult participant to participate