Protocol Title

Mindful After Cancer Study: Fostering positive body image, sexual health, and well-being

Principal Investigator

Jessica R. Gorman, PhD, MPH

Sponsor

Oregon Health and Sciences University

Knight Community Partnership Program

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1.0 Study Objectives

The study aims are to: 1) Assess the feasibility of the MAC program when delivered via videoconference and 2) Assess preliminary effects of the program. The long-term goal is to establish a strategy for program sustainability, and to improve quality of life for breast/gynecologic cancer survivors in Oregon.

2.0 Background

The inspiration for this project stemmed from the unmet sexual health-related needs and concerns expressed by the local cancer survivor community, which resulted in a partnership between OSU and Samaritan Cancer Resource Center to begin filling this gap. Our community's concerns were not surprising given that the sexual health consequences of cancer are among the most common and distressing aspects of survivorship. All participants in our prior pilot trial were experiencing clinical levels of sexual distress and dysfunction. Overall, at least half of breast and gynecologic cancer survivors experience sexual health difficulties. Concerns extend beyond the capacity to have sexual intercourse, and encompass physical, psychological, and social aspects related to physical discomfort, low desire, mood, body image, and worries about partners' satisfaction. Tools such as lubrication and dilators can help with physical challenges, but the emotional and social aspects are equally critical, and all aspects are addressed in this program. Importantly, when sexual health concerns are left unaddressed, there is a negative impact on partner relationships and quality of life well after cancer treatment ends.

In the earlier phase of this study, we made initial adaptations to an evidence-based intervention based on cancer survivor and stakeholder feedback. There is evidence that the prior version of the intervention (MIND) improves sexual function among women in the general population, and we made adaptations to the content to meet the needs of women who had survived cancer. We conducted interviews with the target audience to understand their characteristics, experiences, attitudes, needs, and potential facilitators and barriers to their participation in the intervention. As part of the iterative adaptation process, following the ADAPT-ITT model, we pre-tested the newly adapted intervention with a group of female cancer survivors. Data from this first phase of research provided evidence for feasibility and acceptability, as well evidence of the intervention's capacity to improve sexual and psychosocial health outcomes for female cancer survivors. This process also resulted in adaptations to make the program easier for the facilitator to deliver and participant materials tailored to the needs and concerns of cancer survivors. Results pointed toward the potential of a videoconference-based delivery mechanism to help overcome barriers associated with time/travel, privacy concerns, and preference for receiving the intervention in home or community settings (vs. a cancer care setting). The current phase of research will build on this prior work to further optimize the intervention for breast and gynecologic cancer survivors and to increase the reach of this intervention to survivors across Oregon. This work has occurred in consultation with the original developer of the materials.

3.0 Research Procedures

Intervention with pre-post assessment and follow-up qualitative interview with sub-group.

The 8-week intervention will be offered for 15-25 survivor participants per group via videoconference across 2 different cohorts. A trained facilitator will deliver the intervention by following a detailed manual. Participants will have companion handouts and activities for in session activities and home activities. Each weekly session is 1.5-2 hours long. Participants will connect via videoconference from a private location via their computer, tablet or smart phone. Participants may either connect using a video camera if they choose to, or they may choose to interact using only audio. Prior to the start of the program, we will provide tutorial information about use videoconference software and a phone number to call in case of technical difficulties. We will also mail each participant a hard copy of all participant materials, which include home activities and educational materials. Each week, we will provide them with an audio-recorded meditation to use at home.

At the end of each session, the facilitator will remind participants that they can reach out to her between sessions if needed, and how to reach her (e.g., email, phone). She will also remind participants of the online and telephone-based resources available to them should they need extra support between sessions. Participants who are experiencing difficulty will be encouraged to seek support via professional counseling/therapy and/or a support group. Participants will be asked to complete weekly tasks (e.g., guided meditation, homework activities) as part of the invention. Data from these tasks will not be analyzed for purposes of this study.

All participants will receive a Qualtrics link after enrolled, and prior to the start of the intervention, so that they can complete an online baseline survey. They will receive a second link to complete an online survey 1-month after the intervention ends. Surveys will evaluate acceptability, credibility, and changes in sexual function, psychosocial health, relationship outcomes, well-being, and sex-related distress.

To evaluate quantitative data, we will use a dependent groups t-test or Wilcoxon test to compare mean/median scale scores (pre- and post-test) for each outcome assessed. Our focus for this study is on the feasibility and acceptability of the intervention, and implementation using a videoconference format. With the small sample size, we do not anticipate having sufficient power to detect pre-post changes in outcomes.

Sampling strategy for qualitative interviews: We will use purposeful sampling to select 10 participants that represent maximum variation. We will purposefully invite women who are reproductive-aged and post-menopausal, breast and gynecological cancer survivors, women who identify as white and non-white race, and women who identify as heterosexual and non-heterosexual. We expect this strategy to yield representativeness and diversity in the sample, and to improve documentation of the potential variations and common patterns (e.g., needs, preferences) that cut across cases.

This will allow us to gain valuable knowledge about participants' experiences with the intervention, in behavior, facilitators of change, barriers to change, additional intervention modifications, and the context and meaning for any perceived changes in sexual function, psychosocial health, relationship outcomes and other outcomes of interest. Eliciting the experiences of participants through in-depth post-intervention interviews will improve our understanding of how the intervention works.

We will transcribe post-intervention interviews and will use cross-case, inductive analysis to analyze responses and identify themes and patterns in the qualitative data. To enrich our understanding of the program's impact, we will consider quantitative results within the context of qualitative findings.

Participant intervention sessions will be audio recorded for review and assessment of fidelity of intervention delivery. This is required for participation. Post-program qualitative interviews will be audio recorded for later transcription to ensure the collection of accurate interview data.

In all cases, participants must agree to audio-recording in order to participate. They may choose not to answer any of the questions. They may choose to end the interview or leave an intervention session at any time. Audio recording is necessary for the collection of accurate interview data and for the assessment of fidelity (delivery of the intervention as outlined in the protocol). In the case that a participant initially agrees to audio recording an interview and requests that the recording is stopped before completing the entire interview, the interview will be terminated but the interview data to that point will be included in the study.

4.0 Inclusion and Exclusion Criteria

4.1 Inclusion Criteria

Adult female breast/gynecologic cancer survivors| This group experiences a direct, negative impact on their reproductive systems, leading to concerns about body image and sexual function. We focus on females because their sexual concerns are distinct from and more poorly addressed than males' concerns.

Diagnosis 1 or more years prior and completed primary cancer treatment. Research indicates that post-treatment cancer survivors are at highest risk of sexual health concerns. Participants in our pilot trial also confirmed that this group would benefit most from the intervention.

Have access to a computer, smart phone, or tablet with internet access. This is required for those who to be eligible to participate in the program.

Ability to spend 15-30 minutes daily on program activities | This was determined to be feasible in the first phase of research, and will be sufficient to complete required intervention activities.

4.2 Exclusion Criteria

Cancer stage: Stage 0 cancer (carcinoma in situ) is excluded.

5.0 Risk to Participants and Risk Mitigation

The risks involved in this study are minimal, and consist principally of the possible stress or embarrassment produced by responding to questions during individual interviews, surveys, or

while participating in the intervention sessions. All participants will be assured that they may refuse to answer any question and can choose not to participate in any study activity. There may be psychological distress associated with talking about sexual health or distress caused by participating in a program that brings up sensitive topics to cancer survival and sexual health. Based on our past experiences using these same procedures, the likelihood of and seriousness of these risks to participants is minimal.

The PI and study team members will be sensitive to the fact that participants could be upset because of the topics being discussed. The PI will make sure that the research assistants receive training in communication on sensitive issues and will be respectful of participants to minimize any potential stress.

During interviews, participants may choose not to answer any questions or participate in any aspect of the discussion that they are uncomfortable with. Participants may ask for the recording to be stopped at any time. If during an interview a participant appears particularly uncomfortable or stressed, the interviewer will remind the participant that she/he does not have to answer the question. For all surveys, participants may choose not to answer any question.

During the intervention, participants may choose not to engage or participate in any aspect of the program (e.g., activity, discussion), may leave a session early, and may choose not to attend sessions. Because of the sensitive subject matter, we will provide a listing of "Helpful Resources" to all cancer survivor participants as part of the informed consent procedure.

6.0 Potential Benefits to Participants

There are no known benefits to participating in the study, although participants in the intervention may experience benefits to their sexual and mental health. Our pilot test data provided promising results, including improvements in sexual and mental health outcomes. For all participants, there is a societal benefit of contributing toward an improved understanding of what helps women who have survived cancer to improve their sexual health and quality of life.

7.0 Cost to Participants

Participation in this study requires no cost to participants, aside from time, telephone use, and Internet use.

8.0 Recruitment Process

We will invite participants via social media and community-based outreach via community partners across Oregon. We will invite community partners (e.g., non-profit organizations, clinics, social services, advocacy organizations) to post flyers describing our project. Interested individuals will be asked to contact study personnel for more information and to determine their eligibility.

9.0 Screening and Consent process

Study staff will describe the study to potential participants over the telephone, and will clearly present the eligibility criteria to potential participants and then ask if they are still interested in participating. After obtaining written informed consent to participate, study staff will confirm eligibility criteria and schedule interviews and other study activities. We will retain de-identified screening data for all potential participants so that we can report the number of screened, eligible, and enrolled participants by demographic.

Cancer survivors who are recruited to participate in the 8-week program will be required to review and sign the written consent form prior to completing any study activities (e.g., surveys or program meetings). A copy of the signed informed consent will be provided to study participants. Consent forms will be reviewed over the telephone. Each participant will be mailed or emailed the consent form for their signature and it will be returned via mail or in person to study staff prior to completing any study activities.

Those with diminished capacity to consent will not be enrolled. The capacity to consent is initially judged by the study staff at the time of enrollment based on the person's ability to understand the research process as demonstrated during the initial description of the study and their ability to engage in the informed consent discussion. Those with limited ability to engage in the informed consent discussion or limited comprehension of the study requirements will not be enrolled. To assist in determining comprehension, interviewers will ask, "What questions can I answer for you?"

Participants will be asked in the consent form if they are willing to be contacted about future research studies. They can answer yes or no. Participants may also request that we stop contacting them at any time. Participants will not be contacted in the future for the sole purpose of updating information.

The consent form will notify participants that we will keep de-identified data from the study indefinitely. Data will be stored electronically without any personal identifying information and will only be accessible to study personnel. Keeping data will allow us to continue to answer new research questions that may arise and to compare these results to those of future studies. The consent form includes information about how to withdraw from the study, and how to withdraw study data.

10.0 Compensation

<u>Aim 1. Intervention Assessments</u>
Participants in the intervention will receive $20 upon completion of the pre-program survey and $20 upon completion of the post-program survey.

A sub-group of 10 intervention participants will receive $30 for participating in a follow-up qualitative telephone interview.

11.0 Data Management

All participants will be assigned a study-specific identifier. An electronic database file linking a participant to her/his study identifier will be maintained in a password-protected database that can be accessed only by the investigators and study staff. Personal identifiers will be stored securely by study personnel at OSU and retained for future study recruitment.

Potential risks related to the loss of confidentiality will be handled by restricting access to audio-recordings, electronic files, and paper files to designated study personnel. All project data (digital, audio, paper) will be maintained at OSU in locked file cabinets and/or on a password protected computer with fully patched operating systems and applications and current antivirus software with current virus definitions in the locked offices of the PI and trained project staff at OSU. Data will be stored for a minimum of three years after study termination. A plan for routine back-ups is in place.

In written reports and publications, including information shared funders, personal information and identifiers will not be linked to the data. For example, publications may include direct quotes but will only attach a general description of the participant to the quote, such as "breast cancer survivor." We will not use participant names or other information that could identify them personally in reports and publications.

A link between study code numbers and direct identifiers will be retained until analyses are complete, and results have been disseminated via publications and reports. This will allow us to verify details if needed (e.g., if there is a discrepancy or missing data). Audio recordings will be retained until all analyses are completed, and results have been disseminated via publications and reports. This will allow us to verify details from the original data source when creating these reports as needed.

11.1 Data Security

Qualtrics automatically collects IP addresses for survey participants. The survey settings will be adjusted to eliminate collection of IP addresses. Qualtrics will generate personal links to surveys. Study staff will send the link to each individual participant's email. Participant emails will not be shared with Qualtrics. Data are stored separately from personal identifiers.

We will deliver the program remotely, via videoconference. We will audio record program sessions to monitor adherence to the curriculum. We will select the box to audio-record sessions. We will save a copy for our research purposes only.

We will follow best practices to maintain security during videoconference meetings. This includes locking the room before the meeting, checking names before allowing attendees to join, restricting access once all attendees have joined, using a complex password for every meeting, confirming attendance with first name roll call, and using password protection for audio recordings of the meetings.

11.2 Record Retention

Personal identifiers will be stored securely by study personnel at OSU, and retained for future study recruitment. De-identified data will be stored for use in future related study questions, such

as comparing results of this intervention to a future comparison intervention. The PI will be responsible for storing all research related materials for a minimum of three years post study termination.

13.0 Statistical Analysis Plan

Demographics and participant characteristics will be summarized using descriptive statistics. Feasibility measures include enrollment in the study, retention in the study, and retention in the intervention and will be calculated as total numbers and percentages. Scale scores will be evaluated using means and standard deviations. Means and standard deviations at baseline will be compared to means and standard deviations at post-intervention follow-up. The focus for this study is on the feasibility and acceptability of the intervention, and implementation using a videoconference format. With the small sample size, we do not anticipate having sufficient power to detect pre-post changes in outcomes. We will calculate changes in scores, but our focus will be on estimating effect sizes for a future larger study.

For qualitative analysis, transcripts will be analyzed using structural coding, with codes developed directly from the interview guide. At least two members of the team will develop the codebook and complete initial coding. Once the team finalizes the codebook, team members will independently code each interview. Constant comparison method will ensure coding consistency. Codes will be grouped into broader thematic categories that describe patterns in the data related to feasibility. The team will meet frequently to discuss results and employ memo taking to remain reflexive.