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Healthy lifestyle intervention for African American uterine cancer survivors: Study protocol

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ABSTRACT

Background: Cancer of the uterine corpus is the most common gynecologic malignancy and the fourth most common cancer in U.S. women. There is a racial disparity in the survival from endometrial cancer and this may be addressed by culturally-tailored lifestyle interventions to help African American (AA) endometrial cancer survivors lose weight or maintain a healthy weight.

Objective: The overall purpose of this pilot study is to develop and evaluate a culturally-tailored lifestyle intervention to help AA uterine cancer survivors reduce their risk of cancer recurrence and improve their quality of life through healthy eating, physical activity, and weight management. While many interventions have been evaluated to assist cancer survivors through diet and physical activity, few have focused on AA women with a uterine cancer diagnosis.

Methods: Community-engaged research principles are being followed. This study was developed with input from the Augusta University (AU) College of Nursing Community Advisory Board (CAB) and the Division of Gynecologic Oncology at the Georgia Cancer Center at AU. Weekly sessions throughout a 12-week intervention will include physical activity and lectures on improving nutritional status. The pre/post-test design includes baseline and 6-month follow-up, where participants will complete a questionnaire that assesses knowledge and attitudes about physical activity, nutrition, uterine cancer, social support, and quality of life.

Conclusions: From this pilot study, we will learn more about the feasibility and integration of healthy lifestyle interventions in this patient population, and the results can provide an opportunity for a larger-scale, multicenter study with a randomized controlled design.

1. Introduction

Cancer of the uterine corpus is the most common gynecologic malignancy and the fourth most common cancer in U.S. women. In the U.S., Black women have an 80% higher uterine cancer mortality rate than white women [1]. The 5-year survival rate of endometrial cancer patients is 64% for non-Hispanic Black women compared with 86% among non-Hispanic white women [2]. Several factors likely account for these disparities including socioeconomic status, stage-at-diagnosis, tumor characteristics, barriers to access to care, and treatment decisions [2,3]. Higher rates of comorbidities, such as obesity and diabetes, may also have a role. Compared to their white counterparts, African American (AA) patients with endometrial cancer are more likely to be obese or morbidly obese [3]. In addition, AA women who have been diagnosed and treated for uterine cancer have a higher risk of diabetes and impaired quality of life than whites [4]. Black-white differences in uterine cancer survival suggest that there are unmet needs among these survivors.

A small number of intervention studies have examined the feasibility and efficacy of lifestyle interventions aimed at increasing physical activity or improving nutritional status among uterine cancer survivors [5–8]. One additional study focused on both endometrial and breast

Abbreviations: AA, African-American; ACS, American Cancer Society; AICR, American Institute on Cancer Research; AU, Augusta University; BMI, body mass index; CAB, College of Nursing Community Advisory Board; CSRA, Central Savannah River Area; HBM, Health Belief Model; HHS, U.S Department of Health and Human Services; FFQ, Food frequency questionnaire; IRB, Institutional Review Board; PA, physical activity; S-TOFHLA, Shortened Test of Functional Health Literacy in Adults; SUCCEED, Survivors of Uterine Cancer Empowered by Exercise and Healthy diet; TPB, Theory of Planned Behavior; UCSs, uterine cancer survivors; USDA, U.S. Department of Agriculture

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cancer patients [9]. However, none of the studies specifically targeted AA or used interventions that were culturally tailored for African American women. Basen-Engquist et al. [5] conducted a study in which one hundred post-treatment Stage I–IIIa endometrial cancer survivors participated; only seven of the women (7%) were non-Hispanic African American. Von Gruenigen et al. [6] conducted a randomized controlled trial in early stage endometrial cancer patients (n = 45), and all but one of the participants were white. In the SUCCEED Trial, of the 75 overweight and obese endometrial cancer survivors in Cleveland, Ohio randomized to a 6-month lifestyle intervention or usual care group, only 5 of the women (6.7%) were African American [7].

Additional research is needed to examine the effects of life-style interventions among African American uterine cancer survivors. Engaging in behaviors such as physical activity, avoiding tobacco use, eating a healthy diet (e.g., a diet low in fat and high in fruits and vegetables), and learning stress-reduction techniques offers cancer survivors control over their health and may lessen their fear of disease recurrence or progression [10]. This pilot study will help to fill in current gaps in the evidence base on uterine cancer survivorship among African American women.

We hypothesize that: 1) the lifestyle intervention will correspond with a statistically significant increase in daily/weekly physical activity from baseline to six months, mediated by a decrease in perceptions of exercise barriers and improvements in physical activity knowledge and awareness 2) the lifestyle intervention will be associated with a statistically significant improvement in quality of life in pre/post-test comparisons, and that this quality of life improvement will be mediated by improvements in nutritional status.

2. Methods

2.1. Study development

In this community-engaged research study, input has been sought from the Augusta University College of Nursing Community Advisory Board (CAB), which is primarily comprised of African American women who live in Augusta and the surrounding area. The other partner in this project is the Division of Gynecologic Oncology at the Georgia Cancer Center at AU. These members offered input and guidance about recruitment of research participants and planning for the 12-week intervention including appropriate locations for the 12-week intervention, appropriate time and day for the weekly sessions, and the best approach for formatting physical activity sessions. The CAB will continue to provide input throughout the planning and conduct of this study and the dissemination of the results. This will help ensure that the intervention is culturally appropriate.

2.2. Study population

The Gynecological Oncology Program is part of the Department of Obstetrics and Gynecology at the Medical College of Georgia (MCG) at Augusta University. The program provides patient services for women across the Central Savannah Regional Area (CSRA). Gynecologic oncologists will be screening potential participants who meet the following eligibility criteria: African American; stages I or II uterine cancer survivors; at least 3-month time lapse since most recent cancer treatment; BMI > 18.5 (those not underweight); medical clearance for physical activity.

2.3. Recruitment

Prior to participant recruitment, the study will receive approval from the Augusta University IRB. Because research indicates that cancer survivors often develop recurrent or secondary malignancies and other obesity-related disorders, gyn-oncologists at Augusta University Medical Center will identify eligible patients during routine follow up visits post uterine cancer treatment. The gyn-oncology medical staff will explain the research and ascertain patient interest. Potential participants will be asked to sign a release form allowing their contact information to be provided to the research team. Participants will be mailed a letter with additional information about the study and a detailed consent form, followed by a telephone call. During the call, we will use a telephone screening protocol based on the Physical Activity Readiness questionnaire (PAR-Q) (www.csep.ca/forms). Research team members will contact potential participants to determine eligibility, further discuss the research, answer any questions, and schedule a baseline interview. We anticipate that our participants will have comorbidities. Therefore, to increase external validity and to avoid excluding individuals who would benefit from the intervention, those participants that answer “Yes” to any questions on the PAR-Q will not be excluded, but will require medical provider clearance.

2.4. Theoretical framework

The intervention will incorporate elements of the Health Belief Model (HBM), such as educational information about modifiable causes of cancer and other chronic diseases (e.g., the potential benefits of weight loss through healthy eating, caloric restriction, limiting alcohol intake, and physical activity) [22]. We will use the Health Belief Model as the guiding principles for the intervention. The HBM posits that a person's beliefs about a health concern, such as cancer recurrence, their perceived benefits of an action (e.g., adopting a healthy diet, engaging in physical activity, avoiding alcohol and tobacco) barriers to action, and self-efficacy explain engagement in health promoting behavior [22]. The HBM suggests that a stimulus or cue to action must be present to trigger health-promoting behavior. The lifestyle intervention will also incorporate elements of social cognitive theory [20] including goal setting, self-reporting of dietary intake self-monitoring of minutes of physical activity per day, and reinforcement of positive behaviors. Self-monitoring is strongly associated with behavior change [21]. The intervention will provide several triggers to promote healthy behaviors, and participants will be able to track minutes of daily physical activity. To increase self-efficacy, the intervention will provide information about practical steps that can be taken to lose weight or to maintain a healthy weight including menu suggestions. Other topics that will be discussed incorporate portion sizes, meal planning, food labels, grocery shopping, eating out in social situations, and improving overall diet quality. The sessions will include instructions for setting individualized goals, tracking progress, and receiving feedback. The intervention will allow users to set a weight loss goal and to self-monitor daily dietary intake toward achieving that goal and serve as a cue for action.

2.5. Intervention development

The intervention developed for this study will incorporate existing physical activity, and nutrition interventions that have been developed for uterine cancer survivors [5–8] and African American and white breast cancer survivors [10–20]. To pretest draft intervention materials, we will hold two focus group sessions with 8–10 AA uterine cancer survivors per group. We will present the draft materials to the focus group participants to solicit their feedback and input on improving the materials, including the ease and time required for completion of questionnaires. This will help to ensure that the materials are acceptable to the target population, persuasive, and more likely to be effective in changing behaviors. Members of the CAB will also be asked to review draft intervention materials in order to solicit their ideas about how to improve them.

Education and skills development to increase physical activity will be adapted from intervention materials used in previous studies of uterine cancer survivors and African American breast cancer survivors (see Table 1). During the 12-weekly group sessions, participants will have opportunities for facilitated physical activities. The goal will be to