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Protocol and recruitment results from a randomized controlled trial comparing group phone-based versus newsletter interventions for weight loss maintenance among rural breast cancer survivors ☆

Christie A. Befort [a,*], Jennifer R. Klemp [a], Carol Fabian [a], Michael G. Perri [b], Debra K. Sullivan [a], Kathryn H. Schmitz [c], Francisco J. Diaz [a], Theresa Shireman [a]

[a] University of Kansas Medical Center, 3901 Rainbow Blvd, Kansas City, KS, USA
[b] University of Florida, PO Box 100185, Gainesville, FL 32610, USA
[c] University of Pennsylvania, Perelman School of Medicine, 423 Guardian Drive, Philadelphia, PA 19104, USA

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ABSTRACT

Obesity is a risk factor for breast cancer recurrence and death. Women who reside in rural areas have higher obesity prevalence and suffer from breast cancer treatment-related disparities compared to urban women. The objective of this 5-year randomized controlled trial is to compare methods for delivering extended care for weight loss maintenance among rural breast cancer survivors. Group phone-based counseling via conference calls addresses access barriers, is more cost-effective than individual phone counseling, and provides group support which may be ideal for rural breast cancer survivors who are more likely to have unmet support needs. Women ($n = 210$) diagnosed with Stage 0 to III breast cancer in the past 10 years who are ≥3 months out from initial cancer treatments, have a BMI 27–45 kg/m^2, and have physician clearance were enrolled from multiple cancer centers. During Phase I (months 0 to 6), all women receive a behavioral weight loss intervention delivered through group phone sessions. Women who successfully lose 5% of weight enter Phase II (months 6 to 18) and are randomized to one of two extended care arms: continued group phone-based treatment or a mail-based newsletter. During Phase III, no contact is made (months 18 to 24). The primary outcome is weight loss maintenance from 6 to 18 months. Secondary outcomes include quality of life, serum biomarkers, and cost-effectiveness. This study will provide essential information on how to reach rural survivors in future efforts to establish weight loss support for breast cancer survivors as a standard of care.

1. Introduction

Body weight has a negative impact on breast cancer outcome, with women who are obese at diagnosis having higher risk of recurrence and death compared to their normal weight counterparts [1–4]. In addition, weight gain is common after diagnosis particularly in women who receive systemic therapy and become post-menopausal [5,6] with some [7] but not all [8] studies showing increased risk of recurrence with clinically significant weight gain. Biochemical mediators of obesity-associated risk are thought to be hormones, insulin, and adipocytokines [9,10]. Obesity-related comorbid conditions such as heart disease and type 2 diabetes are also a common concern in the long-term care of breast cancer survivors [11,12].

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* Corresponding author. Tel.: +1 913 588 3338.
E-mail addresses: cbefort@kumc.edu (C.A. Befort), jklemp@kumc.edu (J.R. Klemp), cfabian@kumc.edu (C. Fabian), mperri@phhp.ufl.edu (M.G. Perri), dsulliva@kumc.edu (D.K. Sullivan), schmitz@mail.med.upenn.edu (K.H. Schmitz), tshirema@kumc.edu (T. Shireman).

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Given the strong observational evidence linking obesity and physical inactivity [13–15] with poor breast cancer prognosis, large-scale randomized clinical trials are needed to test the effect of intentional weight loss on breast cancer recurrence and mortality. In the meantime, intermediate trials are needed to demonstrate ability to produce long-term weight loss maintenance and associated biomarker modulation in a cost-efficient way that can also be extended to underserved and hard-to-reach survivors.

Nearly 20% of women in the U.S. reside in a rural area [16] representing one of the largest medically underserved populations in the nation [17] and one of the most understudied groups of breast cancer survivors [18]. Rural women are more likely to be obese [19] and have lower physical activity levels [20–22]. Delivering evidence-based behavioral weight control treatment to rural areas remains a challenge. The standard treatment schedule typically includes face-to-face weekly sessions for 16 to 26 weeks [23] followed by extended maintenance care for 1 to 2 years [23,24]. Barriers in rural areas to this traditional high intensity approach include transportation distance and limited availability of trained health counselors. Among web- and phone-based alternatives, phone-based treatment has the greatest reach for rural areas where televideo capacity is limited to sparsely located clinics and only 55% of residents have home broadband internet access [25]. Moreover, studies have demonstrated greater weight loss maintenance with individual phone counseling compared to mail [26], email, and web-based interventions [27,28].

Compared to individual phone counseling, group phone counseling via conference calls has the benefit of diminishing costs and capitalizing on the mechanisms of in-person groups by allowing participants to interact with each other in real time [29]. Group treatment has been shown to outperform individual treatment for weight loss [30,31] presumably due to group support, problem-solving, and accountability [29,32]. Group phone counseling may be especially ideal for rural breast cancer survivors who often report unmet support needs and no contact with other survivors [18,33,34].

This study is a 5-year randomized controlled trial in rural breast cancer survivors designed to examine two alternatives for delivering extended care for weight loss maintenance after a 6-month group phone-based weight loss phase. Subsequent to the weight loss phase, participants are randomized into one of two weight loss maintenance strategies: continued group phone counseling or a mailed newsletter comparison arm. The primary endpoint is weight loss maintenance from 6 to 18 months. Secondary endpoints include quality of life, serum biomarkers, and cost-effectiveness across the two arms. The main hypothesis is that continued group phone counseling is more effective as a weight loss maintenance strategy than switching to a lower-cost newsletter approach. The cost-effectiveness endpoint will explicitly value the benefit gained from the more expensive group phone counseling.

2. Methods

2.1. Overview

The overarching objective of the study is to test a delivery strategy that produces meaningful long-term weight loss maintenance, improved quality of life, and breast cancer biomarker modulation, with far-reaching potential for dissemination to rural and otherwise hard-to-reach populations of breast cancer survivors. The study involves 3 phases: 1) a 6-month weight loss phase (0 to 6 months) where all participants receive group phone sessions, 2) a 12-month weight loss maintenance phase (6 to 18 months) where participants are randomized to continued group phone sessions or the newsletter comparison condition, and 3) a 6-month no contact follow-up phase (18 to 24 months) to evaluate sustained effects of the intervention after the two types of extended care ends. The primary endpoint is weight change from 6 to 18 months. Participants are recruited in 8 cohorts, with one phone group and one newsletter group in each cohort.

2.2. Eligibility criteria

Eligible participants are post-menopausal female breast cancer survivors with a body mass index (BMI) of 27–45 kg/m^2, age $\leq$75 years old, who have been diagnosed with Stage 0–IIIc disease within the past 10 years (except Stage 0 with mastectomy only), have completed all local and systemic therapy (including herceptin) at least 3 months prior to entry, and have clearance from their oncologist or current medical provider to participate in a weight control study. Women can be on or off anti-hormone therapy. Participants must reside in a rural area according to the Rural–Urban Commuting Area (RUCA) Codes, Urban Influence Codes, amount of agricultural income, and/or individual commuting patterns [35]. Participants must be able to walk briskly unassisted and without serious medical risk, and all participants complete a 6 minute walk test as a screening tool to confirm self-report ability to walk. Women with pending joint replacements, serious cardiac or pulmonary conditions (e.g., congestive heart failure, chronic obstructive pulmonary disease), and insulin-dependent diabetes are excluded. Participants must have access to a telephone and be weight stable within ten pounds three months prior to entry with no ongoing participation in another formal weight loss program, current use of pharmacotherapy for weight loss, or a history of bariatric surgery. Participants who have serious food allergies or are on a special diet preventing consumption of recommended diet are excluded. Participants who screen positive for current substance abuse [36], major depression [37], binge eating disorder [38], or serious psychiatric conditions are also excluded as they are not deemed good candidates for a behavioral weight loss program.

2.3. Participant recruitment

Recruitment occurred between October 2011 and September 2013 in collaboration with eleven regional cancer centers, hospitals, or clinics in the states of Kansas, Nebraska, and Iowa. Local cancer center partners include members of the Midwest Cancer Alliance, a network based out of the University of Kansas Cancer Center with the goal to foster cancer clinical trials and supportive care throughout the region, and NCI Community Cancer Centers in Nebraska and Iowa. Institutional Review Board (IRB) approval and a HIPPA waiver were granted by the University of Kansas Medical Center and approved at each site. Each collaborating cancer center or clinic provided names and addresses of patients treated for breast cancer in the past 10 years and a cover