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Improving Health Engagement and Lifestyle Management for Breast Cancer Survivors with Diabetes

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Abstract

Breast cancer survivors with type 2 diabetes are at high risk for cancer recurrence, serious health complications, more severe symptoms, psychological distress, and premature death relative to breast cancer survivors without diabetes. Maintaining glycemic control is critical for decreasing symptoms and preventing serious health problems. Many breast cancer survivors with type 2 diabetes have difficulty maintaining diabetes self-management behaviors and achieving glycemic control. Both cancer and diabetes-related symptoms (e.g., physical symptoms and psychological distress) are often barriers to engaging in diabetes self-management strategies. This study evaluates a novel diabetes coping skills training (DCST) intervention for improving breast cancer survivors' abilities to manage symptoms and adhere to recommended diabetes self-management behaviors. The telephone-based DCST protocol integrates three key theory-based strategies: coping skills training for managing symptoms, adherence skills training, and healthy lifestyle skills training. A randomized clinical trial will test the DCST intervention plus diabetes education by comparing it to diabetes education alone. Symptoms, distress, diabetes self-management behaviors, and self-efficacy will be assessed at baseline and 3, 6, and 12 months. Glycosylated hemoglobin (HbA1c) will be assessed at baseline, 6, and 12 months. This study addresses a critical gap in the care of breast cancer survivors by evaluating a novel behavioral intervention to

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improve the management of symptoms, adherence, and glycemic control in breast cancer survivors with type 2 diabetes. Special considerations for this medically underserved population are also provided. The findings of this study could lead to significant improvements in clinical care and beneficial outcomes for breast cancer survivors.

Keywords

Diabetes; Breast Cancer; Self-Management; Coping Skills

INTRODUCTION

Approximately 20% of the more than 268,000 women diagnosed with breast cancer in 2019 will have a diagnosis of type 2 diabetes.[1, 2] Type 2 diabetes is undiagnosed in almost one-third of individuals with the disease,[3] suggesting that an even greater number of breast cancer patients have type 2 diabetes.[4] Breast cancer survivors with comorbid type 2 diabetes are at high risk for breast cancer recurrence,[1, 4–22] have a 38% higher risk of breast cancer-specific mortality, and have a 49% higher risk of all-cause mortality[5] relative to women with breast cancer but without diabetes. For early-stage breast cancer survivors, type 2 diabetes is associated with significantly shorter median disease-free survival (36 vs. 81 months).[8] Together, breast cancer and type 2 diabetes represent a public health crisis.[23–25] A recent report by the American Cancer Society and the American Diabetes Association highlights the significance of this problem.[26] The prevalence of type 2 diabetes is rising rapidly in the U.S.,[27] and represents a growing health problem worldwide.[28, 29] Thus, the number of breast cancer survivors with type 2 diabetes will continue to grow.[24, 25, 28, 29]

Breast cancer survivors with type 2 diabetes experience more severe cancer and diabetes-related physical symptoms (e.g., pain, fatigue), poorer physical functioning, and greater psychological distress than those without diabetes.[30–37] Undergoing cancer treatment often exacerbates pre-existing symptoms (e.g., pain, fatigue, and diabetes-related neuropathy).[38] Women with breast cancer and type 2 diabetes are at greater risk for developing new issues including chemotherapy-induced neuropathy,[39–41] persistent post-surgical pain,[42] and severe cancer treatment-related toxicities, [1, 24, 40, 43–46] and cancer treatments may exacerbate diabetes-related complications.

Type 2 diabetes is a major cause of premature mortality and serious health complications (e.g., stroke, renal failure).[26, 47] Improving appropriate self-management of diabetes can dramatically reduce microvascular events, myocardial infarction, and diabetes-related mortality.[48] Data suggest that hyperglycemia and hyperinsulinemia, which are simultaneously present in most individuals with type 2 diabetes,[25] may play an important role in promoting breast cancer growth and progression.[17–20, 49–58] Thus, for breast cancer survivors with diabetes, maintaining glycemic control may be especially important.[25] However, many breast cancer survivors exhibit poor diabetes self-management behaviors, which negatively impact glycemic control and health outcomes.[38, 59, 60] Efforts to engage in diabetes self-management may be challenged by both cancer treatment-

related symptoms (e.g., fatigue, arthralgia) and type 2 diabetes-related symptoms (e.g., neuropathy).[30, 38, 59] For women with type 2 diabetes, self-management includes physical activity, dietary modifications, medication (e.g., insulin), and blood glucose monitoring (when recommended).[47] Maintaining glycemic control and avoiding diabetes-related complications depends on daily engagement in these self-management behaviors.[61–66]

The present study evaluates a novel diabetes coping skills training (DCST) intervention for improving breast cancer survivors' abilities to manage symptoms, reduce psychological distress, and adhere to recommended diabetes self-management. Although systematic training in skills for coping with symptoms and improving adherence could be beneficial for enhancing breast cancer survivors' engagement in diabetes self-management behaviors, to our knowledge, no study has evaluated the effects of such training in patients with breast cancer and type 2 diabetes.

MATERIALS AND METHODS

A. Study Aims

Our *first aim* is to investigate the impact of the DCST protocol on both cancer- and diabetes-related physical symptoms and psychological distress, which are important factors that signficantly impact women's abilities to manage their diabetes. Our *second aim* is to investigate the impact of the DCST protocol on diabetes self-management behaviors. Our *third aim* is to examine the impact of the DCST protocol on glycemic control. Finally, our *fourth aim* is to examine the impact of the DCST protocol on self-efficacy for managing symptoms and diabetes self-care. This study is being conducted in both a tertiary academic medical center and community cancer clinics to increase the generalizability of findings.

B. Patient Selection

a. Eligibility Criteria—Participants are recruited from a tertiary academic medical center and through community cancer clinics that are part of a cancer network affiliated with the tertiary academic medical center. The cancer network is a collaborative program that partners with community hospitals in medically underserved areas to provide access to oncology care. Eligible participants meet the following inclusion criteria: a) diagnosis of Stage I to III breast cancer, b) diagnosis of type 2 diabetes, c) completed primary treatment (surgery, chemotherapy, and radiation therapy), d) physician verification of ability to participate in the intervention, and e) English speaking. Women who meet any of the following criteria are excluded: a) <21 years of age, b) severe cognitive or hearing impairment as documented in the medical record, c) unable to provide meaningful consent (i.e., impairment such that descriptions of the research are not clearly understood), or d) presence of a health problem that precludes safe participation in the intervention (e.g., recent myocardial infarction, poorly controlled atrial fibrillation).

b. Subject Recruitment—This study was approved by the Institutional Review Board. Recruitment procedures comply with HIPAA guidelines. Patients meeting eligibility criteria are informed about the study in one of two ways. First, the study brochure and letter

describing the study are given to women by a member of their treatment team at the time of an oncology follow-up visit. Second, the study brochure that briefly describes the study and a letter from their oncologist introducing the study are mailed to them. Prospective participants are contacted by telephone by study staff to determine if they are interested in hearing more about the study. For women who express interest in participating, study staff arrange an in-person meeting to further describe the study, confirm eligibility for the study, obtain informed consent, and complete the baseline assessment. The initial study visit ranges from 2–3 hours.

C. Procedures

See Figure 1 for the study design. Planned enrollment includes N=200 breast cancer survivors with comorbid type 2 diabetes (i.e., documented in the medical record), with an anticipated attrition rate of 20% for a final sample size of 160. Following the completion of informed consent, women complete the baseline assessment. All participants receive a single 60-minute, nurse-delivered diabetes education session after completion of the baseline assessment. Next, women are randomly assigned with equal allocation to either: 1) Diabetes Coping Skills Training (DCST), or 2) no additional intervention (i.e., patients only receive the single diabetes education session delivered during the baseline assessment). All patients receive usual health care. Randomization is stratified by clinic site to ensure equal allocation across sites, and is determined by a centralized randomization program. We selected clinic site as a key variable for stratification because the patient populations in these clinics vary demographically and reflect the diverse community settings in which these clinics are located. Following randomization, women in the DCST condition are given the intervention workbook materials and are contacted by the study interventionist to begin intervention phone sessions.

In addition to the baseline assessment, all participants complete follow-up assessments at 3 months (mid-intervention), 6 months (post-intervention), and 12 months. During each of the four assessments, participants complete self-reported measures of physical symptoms, psychological distress, quality of life, self-efficacy, and diabetes self-management behaviors. Participants also complete the 6-minute walk test. To track daily physical activity (i.e., steps and distance), pedometers are set up by study staff during the baseline assessment and are given to study participants. Study staff obtain data from the pedometers during the follow-up assessments. When part of the participant’s recommended diabetes care, participants are asked to bring their home blood glucose monitors to each of the four assessments to collect data regarding the frequency of monitoring over the 12 months of study participation. Hemoglobin A1c (HbA1c) levels are assessed at baseline and again at 6 and 12 months to assess glycemic control. Given that HbA1c provides a measure of the cumulative glycemic history of the preceding two to three months, HbA1c levels are not assessed at 3 months as participants will have recently initiated the intervention. We do not anticipate seeing intervention-related changes in HbA1c until participants have completed the intervention.

Interventions

a. Diabetes Education (1 Session): During the baseline study visit, all participants receive a single, individually-delivered, 60-minute diabetes education session with a study

nurse using tele-video-conferencing (via Skype). This session mimics a traditional, in-person, face-to-face diabetes education session, and enables study nurses to deliver the diabetes education protocol to participants completing assessments at their community-based clinic or the tertiary medical center.

The content of the diabetes education session focuses on providing patients with information about diabetes care as recommended by the American Diabetes Association in 2016[67]: 1) healthy eating, 2) being active, 3) blood glucose monitoring (if applicable), 4) taking medication, 5) problem solving for barriers to care, 6) information about healthy coping, and 7) reducing risks of diabetes-related complications. The nurse works with the participant to establish tailored goals for diabetes self-care including the use of oral medication and insulin, glucose monitoring (if applicable), exercise, and foot care. Participants are provided bullet-pointed notes to assist with following along with the nurse-delivered content during the session, as well as an education workbook to use as a reference at home. The goal of the diabetes education session is to provide patients with the knowledge necessary to be active participants in their diabetes management.

b. Diabetes Coping Skills Training (DCST; 12 Sessions)—The DCST protocol integrates coping skills training for managing symptoms, adherence skills training, and healthy lifestyle skills training. The protocol is delivered via phone. Table 1 provides an overview of the approximate frequency and content of each of the DCST sessions. DCST is delivered by psychologists (PhD or Master's level) over 12 sessions (45 to 60 minutes each) across approximately 6 months. The study interventionists schedule sessions using a faded contact model (i.e., 6 weekly sessions, 3 sessions delivered every two weeks, and 3 monthly sessions), but the session schedule may be altered to accommodate the participant's circumstances (e.g., travel, illness).

Each of the twelve sessions is delivered using the following three-section structure. *1) Home Practice Review:* A review of the participant's goals for diabetes self-management and adherence to these goals is conducted. Patients are provided with encouragement for using adherence, healthy lifestyle, and symptom management skills. If non-adherence is noted, brief problem solving is conducted that directs patients to the relevant adherence and coping skills (e.g., cuing strategies). *2) Skills Training:* Each session includes psycho-education (e.g., information about healthy dietary patterns) and coping skills training for improving diabetes self-management. Coping, adherence, and lifestyle skills training addresses cognitive, behavioral, and emotional factors that influence engagement in self-management behaviors and heighten symptoms and disability. Instruction, modeling, and guided practice are used to teach patients skills for managing symptoms and improving engagement in self-management behaviors. 3) *Skills Application and Goal Setting:* Participants set goals for diabetes self-management and applying skills learned during the intervention. Potential barriers to working toward goals and applying skills are identified and participants develop plans for managing these barriers.

The DCST protocol also includes a home-based physical activity protocol developed by an exercise physiologist specifically for breast cancer survivors with type 2 diabetes. Participants are given information regarding the health benefits of exercise, tips for

exercising safely, and suggestions and instructions for specific exercises. This program includes strategies specifically for breast cancer survivors managing long-term treatment side effects such as lymphedema and neuropathy. All participants in the study are provided a pedometer to track steps and distance. For women in the DCST condition, the pedometer is incorporated into activity goal setting and home practice review of physical activity. Strengthening exercises (15 minutes of resistance exercises, 3 or more days per week) are also encouraged, as strength training has benefits for glycemic control.[68] Individuals are given a set of resistance bands and instructions for using the resistance bands. A strength training program using the resistance bands was developed by an exercise physiologist for this study. Participants are provided with written, pictorial, and video instructions for the strength training exercises; an in-person demonstration is also provided by study staff during the baseline study visit.

A long-term goal of 150 minutes per week of moderate-intensity planned activity (e.g., walking 30 minutes, 5 or more days per week), and 15 minutes of exercises to increase strength (e.g., using resistance bands) on three non-consecutive days per week is encouraged. The interventionists work with participants to set safe and realistic physical activity goals during telephone sessions. Participants may be relatively inactive at the start of the intervention; interventionists assist participants with making gradual and small increases in physical activity working towards the goal of 150 minutes per week of walking (or moderate-intensity activity).[69] The interventionist also helps participants identify activities they enjoy that can easily be incorporated into their lifestyle, and to increase opportunities for physical activity in their daily lives (e.g., taking the stairs, parking further away from the store, completing housework). Intervention fidelity is increased by the interventionists participating in structured training, following a treatment manual, and provision of ongoing supervision with feedback regarding adherence to the intervention protocol.

In addition to the aforementioned diabetes education workbook provided during the diabetes education session, each participant in the DCST arm is provided with a DCST workbook, which includes written information, pictures, and diagrams for all content delivered during sessions as well as a home-based exercise manual providing instruction in physical activity recommendations and exercises. The workbooks provide guided exercises to help women apply the intervention content to their lives.

D. Measures

The measures included in the study assessments have extensive reliability and validity data. Table 2 presents the measures and the time points at which each measure is completed.

Aim 1: Investigate the impact of the DCST protocol on physical symptoms and psychological distress

Subjective, Self-report measures

a. Physical Symptoms

Pain Severity and Interference.: The Brief Pain Inventory – Short form (BPI-SF)[70] measures pain severity and interference in the last week over 9 areas (e.g., general activity, mood, sleep, enjoyment of life).

Fatigue.: The 8-item Patient-Reported Outcomes Measurement Information System Fatigue Scale (PROMIS Fatigue)[71] assesses fatigue over the past seven days.

Neuropathy Symptoms.: The 16-item taxane subscale of the Functional Assessment of Cancer Therapy (FACT)[72] assesses symptoms of neuropathy in cancer patients. Participants rate each item on a 0 (not at all) to 4 (very much) scale.

b. Psychological Distress

Depressive Symptoms.: The eight-item Patient-Reported Outcomes Measurement Information System Depression Scale (PROMIS Depression)[71] is used to assess depressive symptoms.

Symptoms of Anxiety.: The eight-item Patient-Reported Outcomes Measurement Information System Anxiety Scale (PROMIS Anxiety)[71] is used to assess symptoms of anxiety.

Aim 2: Investigate the impact of the DCST protocol on diabetes self-management behaviors

Medication Adherence.—A 16-item measure is used to assess self-reported adherence. This measure is based on the Medication Adherence Rating Scale[73] and our prior studies.[74] Items were revised to assess medication-taking behaviors related to adherence (e.g., forgetting) and capture intentional and unintentional non-adherence over the past month.

Adherence to Diabetes Self-Management Behaviors.—The 12-item Diabetes Self-Care Inventory-Revised[75] is used to assess diabetes self-management behaviors in the past month (e.g., exercising regularly, keeping food records, treating low blood sugar, taking the correct dose of pills/insulin).

Home Blood Glucose Monitoring.—When part of the participant's recommended diabetes care, the frequency of use of home blood glucose monitoring is assessed. Data is obtained from the participant's home blood glucose monitoring device using the manufacturer's freely available software or study staff will manually write down the dates, times, and blood glucose values stored in the device from the last 30 days.

Diet.—The Five-A-Day Consumption and Evaluation Tool (FACET) is a dietary questionnaire that assesses changes in knowledge of, awareness of and access to fruits and vegetables.[76] The Dietary Instrument for Nutrition Education (DINE)[77] is used to assess the amount of fat and dietary fiber in an individual's usual diet.

Physical Activity.—Patient-reported physical activity is assessed using the well-validated International Physical Activity Questionnaire (IPAQ).[78] This seven-item questionnaire assesses the amount of time participants have spent doing moderate and vigorous physical activities in the last seven days. Data is also obtained from participants' pedometers to assess daily steps and distance. The 6-minute walk test is an objective assessment of womens' abilities to exert effort in activity and the degree of pain experienced during activity.[79, 80]

Women walk along an indoor hallway for 6-minutes with the goal of walking as far as possible within the allotted time.

Aim 3: Examine the impact of the DCST protocol on glycemic control

Glycosylated hemoglobin levels (HbA1c) will be obtained and analyzed by LabCorp in peripheral blood. HbA1c provides a measure of an individual's average blood glucose levels during the previous two to three months, and it is the recommended standard of care for testing and monitoring type 2 diabetes.[81] HbA1c is an important indicator of glycemic control as it captures the cumulative glycemic history of the preceding two to three months.[82]

Aim 4: Examine the impactof the DCST protocol on self-efficacy

Self-Efficacy.—Self-efficacy for managing symptoms is assessed using an 8-item modified version of a standard self-efficacy scale.[83] Items are rated on a 10-point scale (1=not certain; 10=very certain) and averaged to create a total score (in our preliminary studies Cronbach's α=.75).[84] Self-efficacy for diabetes self-management is assessed using the Confidence in Diabetes Self Care Scale,[85] which measures self-efficacy for performing 27 diabetes self-management behaviors (e.g., detect low levels of blood sugar in time to correct, ask a friend for help, etc.) and yields a total self-efficacy score. This measure has been used in prior studies of cancer survivors with diabetes (Cronbach's α=.86).[38]

Other measures

Treatment Credibility and Satisfaction.—The Treatment Credibility Questionnaire [86–88] is a 5-item measure of the degree to which patients perceive a treatment as credible and expect positive outcomes (e.g., "How helpful does the therapist seem to you?"; "How confident are you that this treatment will help you manage your symptoms and health concerns?"). The Modified Satisfaction with Therapy and Therapist Scale[89] is a 13-item measure of satisfaction with and global improvement after intervention.

Participant sociodemographic and medical characteristics, health literacy, numeracy, health problems, and chronic life stressors are obtained. These variables will be considered as potential covariates in planned analyses. Participants are also asked about their participation in other programs that may impact the results of the present study.

Medical and Demographic Information.—Medical and demographic information are assessed by self-report (e.g., education, race, marital status, income, ability to pay for medication, health insurance coverage) and through medical record abstraction [e.g., age, height, cancer stage (TNM), ER/PR status, HER2 score, surgery, treatments]. Body weight is recorded at each study assessment. Type of pharmacological treatment for diabetes, duration of treatment, the indication of discontinuation, change in medications, and reasons for medication change or discontinuation are recorded.

Comorbidities and Complications.—The Adult Comorbidity Evaluation Scale (ACE-27)[90] is a 27-item comorbidity index for patients with cancer that assesses the severity of comorbidities. This assessment allows the study staff to identify and grade the

severity of comorbidities via medical record. The Self-Report Disease Burden Scale [91] assesses the experience and interference of 25 different health problems (e.g., angina, depression, hypertension, osteoarthritis, stroke). If it is indicated that a problem has been experienced in the past, participants are asked to rate how much this problem has interfered with their daily activities in the past month. Response options range from 1 (not at all) to 5 (a lot). The Diabetes Complications Index[92] assesses diabetes-related complications. This assessment includes 17 items (e.g., ulcers, cramps, numbness in feet) and a checklist of potential comorbid conditions.

Barriers to Taking Medication.—Twelve items assess barriers to taking medication over the past month.[93, 94] Women rate how often certain situations (e.g., side effects, confusion, problems with injections) made it difficult for them to take their medications each day.

Literacy and Numeracy.—The Rapid Estimate of Adult Literacy in Medicine (REALM) [95] is used to assess health literacy. This assessment is a word recognition test during which participants are asked to de-code or pronounce health-related words. The test takes less than 2 minutes to administer and score. The Newest Vital Sign (NVS)[96] is a 6-item measure of numeracy and literacy in adults. Participants are given a nutrition label and must answer four questions involving understanding and using numbers and two questions involving reading and understanding text.

Chronic Life Stress.—The nine-item Chronic Life Stressors Scale[97] is used to assess stressors across nine domains: general/ambient problems, financial, work, relationship, parental concerns, family, social life, residence, and health issues. Participants also complete a questionnaire asking them to rate the economic pressures and concerns they have personally experienced in the past 12 months or since the last study assessment.[98–101]

E. Statistical Analysis

a. Sample Size and Power—Planned enrollment includes N=200 participants, with an anticipated attrition rate of 20% for a final sample size of 160 participants. The planned sample size was determined based on power calculations for comparisons between the DCST and control group in Aims 1–4, and the proposed mediation analyses for self-efficacy in Aim 4. Power analysis for group comparisons in Aims 1–4 were conducted based on the following assumptions: medium effect sizes (d=.5 or f=.25) based on prior preliminary studies, power of .80, two-sided tests, and a family wise error rate of α=.05 for each aim. A Bonferroni correction was used (i.e., α=.05/number of tests conducted) for each aim. For Aims 1 and 2, the total sample size required for adequate power ranges from N=80 to N=122, when correlations among repeated measures range from .2 to .5, respectively. For Aim 3, the total sample size required for adequate power ranges from N=62 to N=86 when correlations among repeated measures range from .2 to .5, respectively. For mediation analysis in Aim 4, sample size estimates were based on 80% power, α=.05, using a percentile bootstrap test of the indirect effect, and interpolating the standardized parameter estimates of Fritz and MacKinnon.[102] A total sample size of N=124 to N=160 will be required to detect an effect size effect size varying from 0.26 (reasonably small) to 0.39

(medium) for the treatment group to mediator path, and an effect size varying from 0.39 (medium) to 0.26 (reasonably small) for the mediator to outcomes path (i.e., an indirect effect size ranging from 0.07 to 0.10).

b. Analyses of Aims 1, 2, and 3—All analyses will be based on intention to treat (ITT) principles. We will examine incomplete data patterns. Data missing at random will be accommodated by the use of linear mixed models under the assumption of MAR or other approaches as necessary. For Aims with more than one outcome measure we will adopt a simple family-wise strategy for adjusting overall alpha for each aim by dividing alpha by the number of outcome variables examined, with alpha set to 0.05/k where k is the number of outcome variables used in each aim.

The primary analysis will examine treatment group differences in patient-reported outcomes (i.e., physical symptoms, psychological distress, self-management behaviors), daily physical activity (i.e., steps, distance), glucose monitoring (as appropriate), and glycemic control (i.e., HbA1c) using linear mixed-effects models. Patient effects will be entered as variance components to model within-patient correlations over time. We will also fit marginal models that account for within-patient correlations directly using an appropriate correlation matrix without introducing random-effects. As a model building strategy, we will first test a main-effects only model and then include the group × time interaction. We will follow up significant interactions using procedures described in Aiken and West[103] for cross-sectional models, and Preacher et al.[104] for longitudinal analyses. Best models will be selected using BIC information criterion to strike a balance between goodness of fit and model complexity. The outcome variables for Aim 1 will be physical symptoms, physical functioning, and psychological distress measured at baseline, 3, 6, and 12 months. For Aim 2, outcome variables will include patient-reported outcomes (medication adherence, self-management behaviors, physical activity, dietary patterns) measured at baseline, 3, 6, and 12 months and data from pedometers (steps and distance averages per month) and blood glucose monitors (% adherent per week) measured across 12 months of enrollment. The outcome variable for Aim 3 will be HbA1c measured at baseline, 6, and 12 months. Baseline values (baseline assessment value for patient-reported outcomes and measures of glycemic control; average steps and distance in week 1; and % days adherent to monitoring in week 1) of the outcome, demographic, and medical (e.g., comorbidities) variables will be used as covariates, and main effects of time, treatment arm, and time by treatment arm interaction will be included as predictors. Family-wise error will be controlled for within each aim as appropriate. By assessing demographic and medical variables, we may also be able to conduct exploratory post-hoc analyses to examine these variables as potential moderators of intervention effects in order to inform future studies.

c. Analysis of Aim 4—Analyses will examine whether changes in self-efficacy mediate the impact of DCST on study outcomes. We will use similar linear mixed-effects or marginal models as described for Aims 1, 2 and 3. The mediational hypothesis will be addressed using a set of three models: 1) the effect of treatment arm on study outcomes (e.g., patient-reported outcome will include 3, 6, and 12 month differences from baseline), 2) the effect of treatment arm on self-efficacy (outcome will include the changes in 3, 6 and 12 month

measures of self-efficacy from the baseline), and 3) the effect of self-efficacy on study outcomes both measured as differences from their baseline. Following recent work on modeling of mediation and timing in mediational models[105–109] we will fit more parsimonious autoregressive cross-lag (ACL) models using SAS PROC GLM, MIXED or GENMOD/with GEE option, or Mplus.

DISCUSSION

The proposed study addresses a critical gap in the care of breast cancer survivors with type 2 diabetes by evaluating a novel behavioral intervention that aims to improve the management of symptoms, diabetes treatment adherence, and glycemic control. The demands of managing comorbid breast cancer and type 2 diabetes pose a formidable challenge for breast cancer survivors and their health care providers.[23–25] The significance of this challenge is highlighted in the 2010 joint consensus report of the American Cancer Society and the American Diabetes Association,[26] which called for research to develop treatments and improve outcomes for individuals with comorbid cancer and diabetes. Adherence to diabetes self-management has been shown to improve glycemic control and impact survival in patients with type 2 diabetes,[47, 48, 110] raising the possibility that the DCST has the potential to improve survival for women with breast cancer and diabetes. For breast cancer survivors with type 2 diabetes, the cost of non-adherence to diabetes self-management is high in terms of symptom-related disability, serious health complications (e.g., stroke, kidney failure), and premature mortality.[24, 25]

This clinical trial will be the first to evaluate a behavioral intervention for breast cancer survivors with type 2 diabetes, and its findings could lead to significant improvements in clinical care, beneficial outcomes for breast cancer survivors, and stimulate new research. If the DCST intervention is efficacious, results from this study could greatly heighten awareness of the role of behavioral interventions in promoting adherence and lead to the inclusion of these interventions in the routine medical management of cancer survivors. Finally, it could facilitate early referral to behavioral interventions before non-adherence leads to serious health problems.

Strengths of the Present Study and Methodological Considerations for the Study Population

The methodologies used in the present study were chosen to address the complexities of this patient population including a greater symptom burden that impacts daily functioning as well as diabetes self-management, competing demands of comorbid health conditions (e.g., increased doctor’s appointments, financial burden, interference with work), and greater life stressors (e.g., fear of cancer recurrence, changes in role functioning due to symptoms). For example, we chose to deliver the intervention sessions via telephone and provide a home-based physical activity program (e.g., home walking protocol, activity tracker, resistance bands with education around use) to reduce barriers to engaging in the intervention. Additionally, the diabetes education session was delivered using video conferencing technology by a trained study nurse. Both the education session and study assessments were

conducted in the patient's local, community-based clinic to reduce barriers associated with parking, travel, and cost (e.g., time and money).

The present study has several strengths. First, the developed intervention combines coping skills training for symptom management with adherence and lifestyle skills training, which is very likely to enhance breast cancer survivors' diabetes self-management. Many breast cancer survivors with type 2 diabetes experience difficult, disabling symptoms (e.g., neuropathy, pain, fatigue) related to both their cancer treatments and their diabetes, and the symptom burden is greater than for those with breast cancer or type 2 diabetes alone;[39–42] these symptoms have a strong, negative impact on diabetes self-management.[37, 111–118] Past intervention work in patients with type 2 diabetes has focused on physical activity and diet, but has not explicitly addressed the physical symptoms that often interfere with engagement in these behaviors. A recent review of clinical trials to promote physical activity in these patients found that no trials targeted pain as part of the intervention or examined pain as a modifier of outcomes.[119]

Second, the DCST protocol is delivered via phone to increase the feasibility of participation among this unique population with difficult symptoms, competing health demands, and limited financial resources. A phone-based intervention confers several important benefits for dissemination, especially for patients who live in medically underserved areas, have lower income, and may be older and less comfortable with newer technologies.[42, 120] First, the financial demands of in-person sessions often prohibit cancer survivors from accessing this type of care, especially those with limited financial resources. Second, many cancer survivors travel a considerable distance to tertiary care centers, making in-person visits challenging. Third, phone-based interventions allow patients to complete sessions from home or a setting of their choosing. Participating by phone from one's home may increase patients' comfort level and ability to generalize skill use to the home setting and community setting.[41] Fourth, phone access is widely available and feasible for most patients. As other forms of communication (e.g., video-conferencing) become more widely available, the DCST protocol could be adapted for these methods of delivery.

Third, given the complexities of this patient population, the diabetes education session was delivered to all participants by a trained diabetes nurse educator, and the DCST intervention sessions were delivered by psychologists. It has been our experience that, even if a patient was diagnosed with diabetes prior to their cancer diagnosis, there are often changes in diabetes management (e.g., movement from oral medications to insulin) that occur following cancer treatment. Regardless of whether a patient was newly diagnosed with type 2 diabetes or had been diagnosed previously, patients may not have access to appropriate diabetes education as their cancer and treatments may have taken precedence during time. In this first trial, clinical psychologists (PhD and Master's level) were chosen to deliver the DCST intervention because of the potential for greater psychological symptoms and the inclusion of skills based in cognitive-behavioral therapy. If found to be efficacious, other psychosocial providers (e.g., social workers, medical family therapists) and diabetes educators (e.g., nurses, nutritionists, dieticians) could be trained to deliver the intervention in the future. Non-behavioral health providers would require specialized training in cognitive behavioral

theory-based strategies given the complexities and greater symptom burden often experienced by these patients.

Finally, if DCST is efficacious, future studies could adapt this intervention to address the challenges affecting cancer patients with comorbid diabetes during adjuvant treatment. Poor glycemic control during chemotherapy is associated with severe side effects and a high risk of severe complications,[24, 43–46, 121–123] which often result in the use of alternative chemotherapy agents or dose reductions.[1, 24, 40, 124–126] The DCST protocol could also be readily adapted to address specific challenges faced by individuals with other types of cancer and type 2 diabetes. For example, type 2 diabetes is prevalent among colorectal cancer survivors,[25] and these individuals often experience difficult symptoms (e.g., chronic bowel dysfunction) that interfere with diabetes self-management. The DCST protocol could be adapted for colorectal cancer survivors by focusing on the application of skills training on these symptoms. Finally, evidence suggests that adherence to healthy lifestyle behaviors is often better when a partner or caregiver is involved.[127–131] Future studies could examine the effects of training both the cancer survivor and their partner/caregiver in the intervention, which could enhance outcomes. [132–134]

Limitations of the Present Study

There are several limitations to be noted. First, this study is limited to breast cancer survivors with diabetes receiving treatment in North Carolina. However, we are recruiting participants from both a major academic medical center and community oncology clinics to capture the impact of the intervention on participants who live in diverse settings. Further, this study only includes breast cancer survivors with diabetes who have completed curative treatment (with the exception of adjuvant endocrine therapy); thus, we are unable to generalize these results to breast cancer patients on active treatment with diabetes, many of whom experience difficulties managing diabetes during surgery, radiation, and/or chemotherapy. Second, participants are followed for 12 months. While this allows us to examine the impact of the intervention over time, the longer-term impact of the intervention on diabetes self-management behaviors will be unknown. If the intervention is shown to be efficacious, future studies may benefit from a longer follow-up period. Finally, medication adherence is assessed using self-report measures. Future studies may benefit from collecting objective data related to medication adherence (e.g., patient medication refill records).

Clinical Implications

For breast cancer patients with type 2 diabetes, avoiding serious health complications depends on daily engagement in diabetes self-management behaviors (glucose monitoring, medication, dietary modifications, and physical activity).[61–66] Yet, breast cancer patients experience significant difficulty engaging in these behaviors during and after treatment, and need support for co-managing their diabetes and breast cancer.[38, 59, 60] Further, cancer treatments (e.g., estrogen suppression due to chemotherapy and/or adjuvant endocrine therapy)[135] may increase the risk of developing diabetes among women with pre-diabetes; thus, this intervention may prove to be beneficial for breast cancer patients with pre-diabetes as well. Future studies could adapt this intervention for use with cancer patients with diabetes during treatment. Studies suggest that chemotherapy and medications commonly

given during chemotherapy, such as glucocorticoids, can dramatically impact blood glucose levels.[38, 45] Finally, results of this trial may provide insight into possible strategies for developing interventions that target individuals with comorbid diabetes and other chronic health conditions or who have symptoms that interfere with diabetes self-management.

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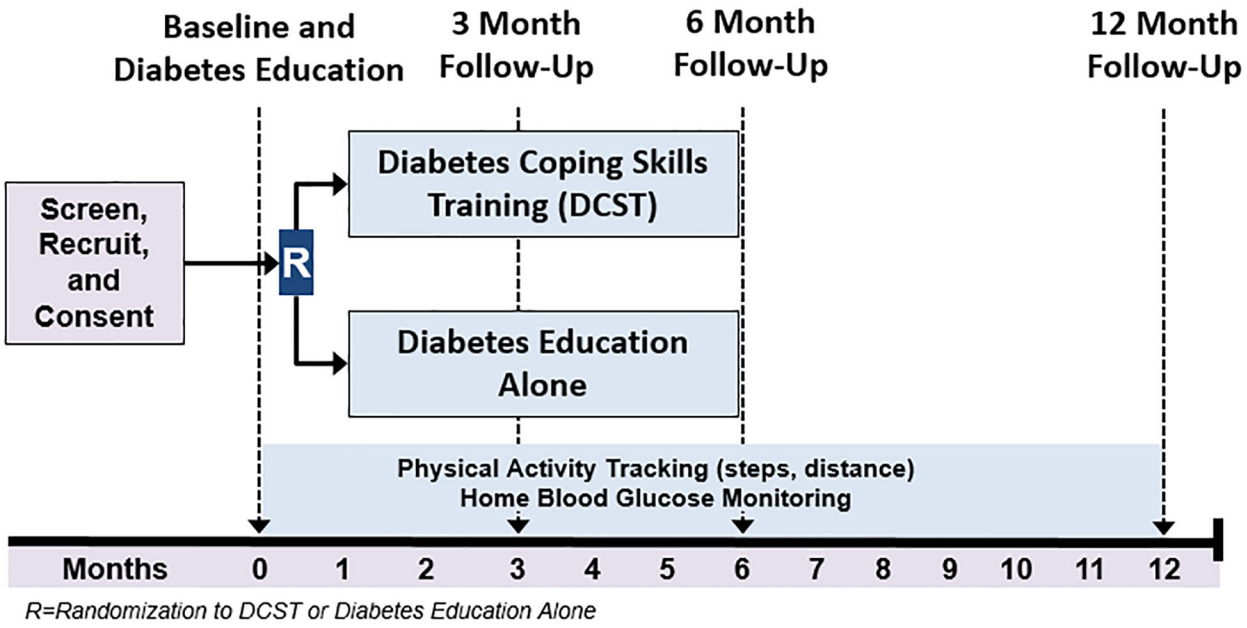

Figure 1.
Study Design

Table 1.

Overview of DCST Telephone Session Frequency and Content

Frequency	Session	Content
Weekly	1	Program introduction and rationale; Diabetes self-management adherence skills; Enjoying an active lifestyle and introduction to the home-based physical activity protocol
	2	Healthy dietary patterns and eating well with diabetes; Staying motivated
	3	Portion control; Stress responses; Relaxation techniques
	4	Brief relaxation and breathing; Activity pacing skills
	5	Increasing lifestyle physical activity; Behavioral activation; Pleasant activity scheduling; Setting SMART goals
	6	Healthy shopping tips; Cognitive restructuring skills: identifying unhelpful thoughts; shifting to more neutral thoughts and using coping thoughts
Every 2 weeks	7	Understanding eating triggers; Managing emotional and environmental eating triggers
	8	Social influences on eating and physical activity; Communicating with significant others; Social eating and eating out
	9	Factors that maintain overeating; Appetite awareness training; Managing urges and cravings
Monthly	10	Food awareness training for portion control and managing urges; Distraction techniques; Enhancing social support
	11	Maintaining change; Problem solving; Plan for skills use and maintaining change
	12	Review of progress; Values; Review of maintenance plans and goal achievement strategies

Table 2.

Timeline of Assessments, Self-report Measures, and Objective Measures

	Assessments				
Construct & Measure	**Daily**	**Baseline**	**3-months**	**6-months**	**12-months**
Aim 1					
Subjective Reports of Symptoms & Symptom Interference					
Brief Pain Inventory- Short Form		X	X	X	X
Patient Reported Outcomes Information System Fatigue Scale		X	X	X	X
Functional Assessment of Cancer Therapy- Taxane Subscale		X	X	X	X
Patient Reported Outcomes Information System Depression Scale		X	X	X	X
Patient Reported Outcomes Information System Anxiety Scale		X	X	X	X
Aim 2					
Medication Adherence					
Revised Medication Adherence Rating Scale		X	X	X	X
Adherence to Diabetes Self-Management Behaviors					
Diabetes Self-Care Inventory-Revised		X	X	X	X
Home Blood Glucose Monitoring (if applicable)	X				
Diet					
Five-A-Day Consumption and Evaluation Tool		X	X	X	X
Dietary Instrument for Nutrition Education		X	X	X	X
Physical Activity					
International Physical Activity Questionnaire		X	X	X	X
Steps and Distance (from pedometers)	X				
6-minute walk test		X	X	X	X
Aim 3					
Markers of Glycemic Control					
Glycosylated Hemoglobin (HbA1c)		X		X	X
Aim 4					
Self-Efficacy					
Self-efficacy for Managing Symptoms		X	X	X	X
Confidence in Diabetes Self Care		X	X	X	X
Other Measures					
Treatment Credibility and Satisfaction					
Treatment Credibility Questionnaire			X		
Modified Satisfaction with Therapy and Therapist Scale				X	
Medical and Demographic Characteristics					
Medical Characteristics (e.g., cancer stage, ER/PR status, Her-2 score)		X	X	X	X
Demographic Characteristics		X			
Adult Comorbidity Evaluation Scale-27		X			
Additional Variables					

	Assessments				
Construct & Measure	**Daily**	**Baseline**	**3-months**	**6-months**	**12-months**
Barriers to Taking Medication		X	X	X	X
Self-Report Disease Burden Scale		X	X	X	X
Diabetes Complications Index		X	X	X	X
Rapid Estimate of Adult Literacy in Medicine		X			
Newest Vital Sign		X			
Chronic Life Stressors Scale		X	X	X	X
Economic Pressures/Concerns		X	X	X	X