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The Breast Cancer Weight Loss (BWEL) Trial (Alliance A011401): A Description and Evidence for the Lifestyle Intervention

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Abstract

The Breast Cancer Weight Loss (BWEL) trial, is a randomized, controlled trial designed to determine whether weight loss after breast cancer diagnosis can reduce the risk of cancer recurrence in women with overweight or obesity. BWEL will compare the efficacy of a telephone-based, weight loss intervention plus health education materials versus health education materials alone on invasive disease-free survival in 3181 women with stage II-III breast cancer and a body mass index (BMI) >27 kg/m^2. In this report, we provide a detailed description of the goals and methods of the lifestyle intervention and the evidence supporting the intervention used in the BWEL trial. The intervention's primary goal for participants is to achieve and maintain a weight loss of ≥ 10% of baseline weight through increased physical activity and caloric restriction. The evidence supporting the diet, physical activity and behavioral components of this telephone-based weight loss intervention as well as strategies to promote participant engagement and retention are described. The intervention is provided through 42 sessions, delivered by trained health coaches, over a 2-year period. If the BWEL lifestyle intervention is successful in improving cancer outcomes, then weight loss will be incorporated into the care of thousands of breast cancer patients.

Keywords

breast cancer; lifestyle intervention; weight loss; diet; activity

Introduction

Obesity has consistently been linked to poor outcomes in women with early stage breast cancer (1-3). A 2014 meta-analysis of 82 studies that evaluated the relationship between body weight and breast cancer outcomes demonstrated a 35% increase in breast cancer-related mortality and a 41% increase in overall mortality in women with obesity at the time of breast cancer diagnosis as compared to those with normal weight (1).

Despite the large body of observational data supporting a relationship between body weight and breast cancer, data on the impact of weight loss on the risk of cancer recurrence and mortality in women with early-stage breast cancer are limited. A number of small- and

medium-sized intervention trials have demonstrated the feasibility of implementing weight loss interventions in post-treatment breast cancer survivors. A 2014 review of 10 randomized trials and 4 single arm studies that evaluated the effect of weight loss interventions in breast cancer survivors reported a loss of more than 5% of baseline body weight in 6 of the 10 randomized trials and 2 of the 4 single arm studies (4). Notably, studies were small, with sample sizes ranging from 10 to 102 participants, and included a variety of intervention types, including in-person group, in-person individual, and telephone-based counseling interventions. Intervention duration ranged from 12 to 52 weeks. Study endpoints included change in health behaviors, weight loss and/or intermediate biomarkers of disease recurrence risk (4,5).

Two large multicenter clinical trials have examined the feasibility and benefits of weight loss interventions in cancer survivors with overweight and obesity. The Exercise and Nutrition to Enhance Recovery and Good Health for You (ENERGY) trial included 692 women and found that the group-based weight loss intervention produced reductions in baseline weight of 6% and 3.7% at 1 and 2 years, respectively, with favorable effects on blood pressure and physical activity (5). The Lifestyle Intervention Study for Adjuvant Treatment of Early Breast Cancer (LISA) study randomized 338 women with stage I-IIIa breast cancer to a 2-year, telephone-based weight loss intervention or to an educational control group. Participants in the weight loss intervention lost approximately 4.5 kg (5.5%) at 1 year and 3.1 kg (3.6%) at 2 years, compared with 0.6 kg (0.7%) and 0.3 kg, (0.4%) respectively, in the control group (6). These studies provide further support that weight loss can be achieved in breast cancer survivors, but it is still not known whether weight loss impacts risk of recurrence and mortality in women with breast cancer.

The Breast Cancer Weight Loss (BWEL) Trial (Alliance for Clinical Trials in Oncology A011401)

The on-going Breast Cancer Weight Loss (BWEL) trial is a randomized, controlled trial designed to determine whether weight loss after breast cancer diagnosis can reduce the risk of invasive disease-free survival in women with overweight or obesity. The protocol for this trial has been previously published (7). As described, the BWEL trial compares the efficacy of a telephone-based, lifestyle intervention plus health education materials versus health education materials alone on invasive disease-free survival in 3181 women diagnosed with breast cancer. Key eligibility criteria include histologic diagnosis of stage II-III, HER-2 negative breast cancer within the past 16 months. Participants must be females ≥18 years of age, have a BMI of at least 27 kg/m^2, be able to read and speak English or Spanish, and have completed all chemotherapy, radiation and surgery at least 21 days prior to study enrollment. Participants with metastatic cancer or diabetes treated with insulin or sulfonylurea drugs are ineligible for enrollment. The trial will additionally examine the efficacy of the intervention on overall survival, development of comorbidities, weight and body composition, quality of life, other patient-reported outcomes and biomarkers linked to breast cancer risk and outcomes (7). BWEL began enrollment in September 2016 in the United States (U.S.) and in September 2017 in Canada. Accrual was completed in February 2021 with 3181 participants

enrolled. Participants will be followed for up to 10 years from trial enrollment to assess survival-related outcomes (7).

The BWEL key intervention components are briefly described in the study's design paper (7). The present report provides a more detailed description of the goals and methodology of the lifestyle intervention and of the evidence supporting the intervention components and strategies as applied in the BWEL trial.

Overview of the BWEL Lifestyle Intervention

The BWEL lifestyle intervention program is based on social cognitive theory (8). Social cognitive theory outlines basic principles that inform most behavior change interventions, which include: 1) acquisition of knowledge; 2) self-monitoring; 3) realistic, incremental goal-setting; 4) problem solving 5) stimulus control; 6) cognitive restructuring; and 7) providing support for change (9).

The lifestyle intervention incorporates treatment components from three randomized weight loss clinical trials: 1) the Diabetes Prevention Program (DPP), designed to assess the impact of an intensive lifestyle intervention (ILI) on incident diabetes in 3234 patients with prediabetes; 2) the Action for Health in Diabetes (Look AHEAD) study, which examined the effect of an ILI on cardiovascular events in 5145 patients with type 2 diabetes and overweight/obesity; and 3) the previously noted LISA Study, a randomized trial designed to evaluate the impact of a remotely-delivered weight loss intervention on disease recurrence in postmenopausal women with hormone receptor-positive early stage breast cancer (6,10-12). BWEL intervention materials were extensively modified from those used in prior trials based on a review of the current literature (13-18) and expert opinion from the BWEL Lifestyle Intervention Committee to reflect advances in weight loss science, as well as breast cancer-specific considerations. A group of more than 10 advocates from the Alliance and Dana-Farber reviewed all patient facing material for tone and clarity.

Table 1 compares the lifestyle intervention goals and methods from the DPP, Look AHEAD, and LISA trials and BWEL. The DPP, Look AHEAD, and LISA interventions focused on energy and fat gram reduction, aiming to reduce energy from fat to less than 20-30% of total intake (6, 10,19,20). Recent studies, however, have recognized the health value of plant-based fat, particularly monounsaturated and polyunsaturated fats, leading to less emphasis on total fat reduction in BWEL (21,22). Additional trials have shown the roughly equivalent weight-loss and health benefit of low-carbohydrate, high-protein diets, as well as other dietary approaches (16-18), relative to the low-fat, high-carbohydrate diets prescribed in the DPP, Look AHEAD, and LISA trials (6,19,20). This led us to offer more dietary options in BWEL, such as high protein-low carbohydrate and Mediterranean-style meal plans, in the study's tool box to allow for better participant engagement and personalization of intervention strategies.

The BWEL intervention was designed to be delivered remotely, recognizing that for the study to be efficient and timely, enrollment of patients would require engagement across hundreds of sites within the U.S. and Canada. Participants are matched with trained health

coaches located at a centralized call center at the Dana-Farber Cancer Institute. Coaching sessions are delivered by telephone and are supplemented with an on-line web portal designed to facilitate communication between coaches and participants; to track changes in diet, activity, and weight; and to increase participant engagement.

The BWEL intervention was developed to offer flexibility to study participants in order to optimize individual weight loss. Intervention materials were designed to be adaptable to individual needs, including cultural diversity of the women enrolled, in order to enhance achievement of health behavior goals. Use of the web portal is optional for participants, allowing women to take part in the study even if they do not have access to the internet. Participants are offered a number of tools to enhance engagement and, in turn, support weight loss, including participant notebooks outlining the session materials, a wireless scale (Aria, Fitbit, Inc), a wearable physical activity monitor (Fitbit, Inc.), meal replacement shakes (Nestle Health Science), a food scale (Ozeri Corp.), and the American Cancer Society Healthy Living Cookbook.

Lifestyle Intervention Weight Loss Goal

The intervention's primary weight-related goal for participants is to achieve and maintain a weight loss of ≥ 10% of baseline weight. With a target 10% individual weight loss goal, a mean study-wide weight loss of about 7%, based on findings from the DPP and Look AHEAD trials (10-12), would be expected. At 1 year, participants in these two studies achieved mean losses of 7.2% and 8.6%, respectively (10-12). The LISA study adapted the DPP lifestyle intervention for women with breast cancer, providing a less intensive intervention, and produced a 5.5% weight loss at 1 year and a trend toward decreased disease-free survival events in the intervention arm (6,23). The individual, aspirational weight loss goal of 10% was selected based on literature suggesting this is achievable through diet and exercise weight loss programs, including in breast cancer survivors, and modulates relevant biomarkers related to breast cancer risk and recurrence (12, 24-26).

Contact Frequency and Delivery Format

The intervention is delivered through telephone-based health coaching calls, which are delivered with more frequent contact in the beginning of the study and decreasing frequency over time. The intervention consists of 12 initial weekly phone sessions, followed by 18 every-other-week sessions for the remainder of Year 1, followed by 12 monthly sessions during Year 2. This translates into a total of 18 sessions during the first 6 months and 42 sessions over 2 years. Contact frequency is based on recommendations from the Guidelines for the Management of Overweight and Obesity in Adults, which prescribes at least 14 treatment sessions during the first 6 months and at least monthly sessions thereafter to promote weight loss maintenance (27). These recommendations are based on findings from multiple randomized controlled trials (RCTs), including by Perri et al, who observed average 6-month weight losses of 7.2% with 8 treatment sessions, which increased to 9.3% with 16 sessions (28). Multiple RCTs have demonstrated benefits of every-other-week or monthly weight loss maintenance sessions for improving long-term (> 1 year) weight management (29).

The BWEL intervention is delivered to individual participants by telephone from a centralized health coaching call center at the Dana-Farber Cancer Institute in Boston and is supported by a web portal and/or print materials. Telephone delivery was chosen for its feasibility of delivery and lower cost, as compared to in-person treatment, its convenience to participants, and prior national studies demonstrating success with this approach in the cancer survivorship setting (30-32). The Guidelines for the Management of Overweight and Obesity in Adults include recommendations for telephone-based weight loss counseling, an approach supported by previous research (27, 33-37). Telephone-based counseling has been shown to be effective in breast cancer populations, with mean weight losses of 4.6-10.6% of baseline weight at 18 months, and good attendance (6, 24,38,39). Individual (as compared with group) telephone delivery facilitates optimal rapport between coaches and participants and allows for tailoring of sessions to the needs of women from diverse racial, ethnic, and socioeconomic backgrounds. This approach was the most pragmatic and flexible from an operational standpoint, given the large number of sites that are recruiting participants from varying time zones throughout the US and Canada. Participants are matched with a lifestyle coach based on scheduling needs (call times range from 8 AM EST to 11 PM EST), and language preference (English, Spanish).

Use of A Centralized Web Portal

The BWEL web portal plays a central role in intervention delivery. The portal acts as a data management system, with participant, coach and administrative domains. Participant use of the portal is optional, but can be employed to view all intervention materials; to track physical activity, weight and dietary patterns; and to communicate securely with coaches. All telephone-based coaching calls are placed through the web portal, directly to participants' telephones, using the VOIP platform Twillio®. All calls are recorded for coach training and quality assurance. Coaches use the web portal for communicating with patients; tracking changes in weight, diet and physical activity; making call notes; and scheduling calls. Administrative functions of the web portal include tracking weight change across study participants and monitoring call frequency and missed calls.

BWEL Treatment Components and Sequencing

Intervention topics (Table 2) and sequencing are adapted for the cancer survivor setting from the Real-Health-Diabetes Study lifestyle intervention (40) (a curated hybrid of key DPP and Look AHEAD sessions) and the Power Up Study lifestyle intervention (41). All session materials were reviewed and approved by members of the BWEL Lifestyle Intervention Committee and breast cancer patient advocates, prior to study implementation.

Sessions 1-4, which are key to establishing rapport between coaches and participants, are delivered in an estimated 45 minutes, with the remaining sessions delivered in 30 minutes. In the first session, coaches welcome and orient participants to the program, the workbook and the website; listen and learn about each individual's past experiences with weight loss, side effects or symptoms from breast cancer treatment and schedule in terms of family, work, and other commitments; and introduce the BWEL study weight loss approach, the 10% weight loss goal and the importance of self-monitoring of food intake, activity and

weight. For the first 10-15 minutes of each follow-up call, the coach asks the participant what she has learned by self-monitoring weight, eating, and physical activity since the last session and by applying the knowledge and skills discussed in the previous session. For the rest of the call, the coach and participant discuss the current session topic (Table 2), its relevance to the participant's lifestyle change process, and behavioral tasks to complete by the next session. Sessions at months 3, 6, 12, 18, and 24 provide participants an opportunity to review longer-term changes in their eating behavior, physical activity, and weight, as well as improvements in knowledge, energy, self-confidence, and other health-related outcomes.

Nutrition Intervention

Given that energy restriction and dietary changes are the biggest predictors of weight loss, with physical activity contributing minimally to weight loss in the short-term (42), initial sessions focus on reducing energy and fat intake (particularly unhealthy fat) and portion control. BWEL nutrition intervention is designed to induce an energy deficit of 500-1000 kcal per day to promote weight loss of 0.5-1.0 kg per week (i.e., 1-2 lb per week). Participants receive one of two calorie target ranges: 1200-1500 kcal/d for women who weigh 113.6 kg (250 lb) or less at baseline and 1500-1800 kcal/d for those > 113.6 kg. Participants receive fat gram target ranges of 20-35% of calories from fat, based on evidence that a variety of macronutrient levels can produce weight loss in the context of an energy deficit (43-45). To enhance learning, participants initially track both calorie and fat gram intake and then to simplify self-monitoring, transition to tracking just calorie intake. To facilitate food selection within energy goals, 7-day meal plans are provided for each calorie target range, with variations of 20-35% fat, 20-25% protein and 40-55% carbohydrate for vegetarian, low carbohydrate-high protein, and Mediterranean style eating patterns.

The nutrition intervention provides commercially-prepared meal replacement shakes (OPTIFAST, Nestle®) that contain 200-225 kcal per serving, with approximately 23-26 grams of protein, 6-8 grams of fat, and 10-17 grams of carbohydrate. Starting with session 4, participants are encouraged to try the meal replacement product and, if found acceptable, to replace 1 or 2 meals per day with shakes (which are provided free of charge) for the remainder of the intervention period. Alternatively, participants can make their own shakes or purchase prepackaged meal replacement bars, soups, or frozen entrees. In non-cancer trials, meal replacement shakes have been shown to significantly increase weight loss as compared with isocaloric, self-selected diets of conventional foods (46). A meta-analysis of 6 randomized controlled trials found that when compared with a conventional diet, the use of liquid meal replacements induced a 3 kg greater weight loss at both 3 and 12 months (47). The use of portion-controlled servings of conventional foods and prepackaged entrees also promotes greater weight loss compared to a self-selected diet with the same calorie targets (48-50). In one weight loss intervention among breast cancer survivors the incorporation of meal replacement shakes and prepackaged entrees in the diet demonstrated a mean 6-month weight loss of 13.9% (24, 51). In qualitative interviews at the completion of that intervention, the women reported that they liked the convenience of the shakes and prepackaged entrees because they required little food preparation time and forethought. They liked the taste of the shakes particularly when they added fruit, and they reported that the prepackaged entrees taught them portion control (51). Additional studies have revealed

similarly large losses in breast cancer survivors, as well as patients with type 2 diabetes who consumed meal replacement products (12, 24, 38,39). The use of commercial meal replacement shakes was optional for BWEL patients. Rates of usage of these products is being tracked and will be evaluated as a part of study analyses.

Nutrition topics in the first 6 months address healthy eating guidelines, nutrition and breast cancer, and strategies for eating out. Nutrition materials after the first 6 months address "volumetrics," which consists of choosing foods that are high in weight or volume but low in calories, such as fruits and vegetables. Consumption of such low-energy dense foods increases satiety and reduces calorie intake at meals and supports maintenance of weight loss (52-55). Topics include building better meals and snacks, ways to control hunger, and feeling full on fewer calories.

Physical Activity Intervention

The physical activity goal is to achieve 150 or more minutes of moderate-intensity physical activity per week, starting with 10-to-15-minutes per session and increasing to at least 30 minutes per session on most days of the week, by the end of 6 months. This goal is consistent with expert recommendations (13,14). Observational studies have demonstrated an association between this level of physical activity and improved cancer survival in women with early breast cancer (13). The goal to gradually increase physical activity to ≥ 225 minutes per week after the first 6 months is based on the American College of Sports Medicine Position Stand on physical activity intervention strategies for weight loss and weight loss maintenance (14,56, 57). Current evidence indicates that physical activity levels ≥ 200 minutes per week are associated with improved weight loss maintenance and help to compensate for increased energy efficiency after weight loss (56,58,59).

The physical activity component relies on at-home exercise rather than a supervised program. At-home exercise was selected for use as it is easier to implement and is potentially associated with better weight loss maintenance (60,61). Starting at week 5, participants are advised to engage in moderately intense aerobic exercise, similar to brisk walking, and to spread their activity minutes across the week with bouts of at least 10 minutes. These recommendations are based on evidence that 4 (10-minute) bouts of activity, distributed across the day, result in improved goal adherence and similar cardiorespiratory fitness compared to 1 (40-minute) bout of activity (62). Participants who are already active develop with their coaches a personalized plan for activity progression based on their current levels of activity. Coaches also worked with participants to explore the availability of local supervised activity programs, such as the LIVESTRONG at the YMCA program, which includes a supervised resistance training program. Additionally, participants who requested resistance training instruction were provided with a FITSTAR program through Fitbit. Rates of usage of this program are being tracked as part of the exercise intervention.

Participants are encouraged to reduce sedentary time as research has suggested an association between being inactive and the risk of developing some cancers including breast cancer (63). Lifestyle activities such as taking the stairs and parking further away from driving destinations are encouraged because they have been found to be as effective as

structured aerobic activities (e.g., a step class) in achieving weight loss and weight loss maintenance (64, 65). To facilitate achievement of ≥ 225 minutes per week, participants are provided with an activity tracker (Fitbit Inc, San Francisco, CA) at week 26 to monitor their physical activity in terms of both active minutes and daily steps. Week 26 was chosen as a time point for delivery of the activity monitor as this marks the transition from the most active period of weight loss to the weight maintenance phase. Participants are encouraged to build up to 10,000 steps per day by the end of Year 1 by adding 1,000 steps per day each month (66-68). Session topics in months 7-24 include ways to step up physical activity, finding time for activity, and getting support for being active.

Behavioral Intervention

The behavioral component of the program begins at Session 1 with the introduction of self-monitoring of weight and food intake, the latter by using either paper records or the Fitbit app technology that interfaces with the BWEL website. In Session 2, participants learn to set behavioral goals to achieve their calorie and fat gram goals shifting focus to only calorie goals at session 4. In Session 5, they learn to set behavioral goals to achieve the physical activity goal and begin to self-monitor physical activity minutes and steps.

Participants are encouraged to weigh themselves at least three times per week and track calories and physical activity minutes daily. Participants are provided with a wireless scale (Aria Scale, Fitbit Inc, California) to allow for centralized collection of body weight measures. Frequent self-monitoring of weight and food intake is associated with greater weight losses and intervention adherence (69-71). Participants and coaches review completeness of self-monitoring records and daily totals and weekly averages for calories, fat, and physical activity minutes. The website displays graphs of weight change over time, daily calories, physical activity minutes and steps, which coaches and participants review on each call. Coaches emphasize the importance of balancing calorie intake over the week in response to weight increases or overeating episodes to increase dietary restraint, which has been shown to predict long-term weight loss with the DPP lifestyle intervention (69). More simplified tracking methods are offered for participants who find standard methods burdensome. In Session 9, participants learn the recommended number of daily servings from each food group that would meet their target calorie range. They are then introduced to the option of using “Rate Your Plate worksheets” to track the number of servings from each food group that they consume each day towards healthy eating goals and calorie targets as a way to simplify self-monitoring.

In the first six months, behavioral topics focus on cue control, problem solving, cognitive restructuring, recovering from slips, and managing emotions. In months 7- 24, topics focus on the knowledge and skills needed for weight loss maintenance. Daily self-monitoring of weight is encouraged to help participants learn to reverse small weight gains as they occur, which is a key skill for maintaining weight loss (72-75). Participants learn to set a “warning weight” defined as the weight at which they commit to take strong action to stop regain and strengthen focus on weight management efforts. Coaches guide participants in developing an action plan for how they will respond to the warning weight when they reach it. The action plans represent each participant’s personal recipe for success and may include weighing

daily, using more structured portion-controlled meals, planning ahead to use best meals and snacks, more careful self-monitoring of food intake, and employing strategies to manage slips, stay motivated and stay positive. Participants complete worksheets between sessions to help them practice the behavioral skills in ways that are relevant to their lifestyle. This improves self-efficacy for managing eating and physical activity habits. Improvement in diet self-efficacy was a key predictor of long-term weight loss in the DPP (72).

ToolBox Strategies

The BWEL lifestyle program incorporates the use of “toolbox” strategies to tailor treatment and optimize behavior change. The use of toolbox strategies is guided by a needs assessment of each participant based on individual barriers to behavior change related to weight loss (or weight loss maintenance) as identified at each session. The efficacy of a toolbox approach has not been evaluated in randomized controlled trials. However, toolbox strategies were used to help participants respond to weight loss and physical activity barriers and enhance outcomes in both DPP and Look AHEAD (19,20). In the DPP, in depth problem solving was the most common toolbox approach that coaches used to help participants deal with ongoing barriers to weight loss and physical activity (76).

Participants who have persistent difficulty limiting calories and fat and/or increasing activity, or who are losing < 1% of weight per month in the first 6 months, are eligible for additional support strategies provided within the program’s toolbox. Use of toolbox strategies can be initiated by either the participant or the coach. Examples of strategies include handouts on exercising with neuropathy; intensifying or simplifying the dietary self-monitoring approach; worksheets to practice problem-solving or goal setting; and study provision of measuring cups and spoons. Coaches also incorporate motivational interviewing techniques (77,78) and additional attention to problem-solving approaches as toolbox strategies (79) to enhance adherence to dietary and physical activity recommendations as these strategies are associated with greater weight loss.

Strategies to Address the Needs of a Culturally Diverse Population

The lifestyle intervention is designed to address the needs of the racial and ethnically diverse population of women with breast cancer and overweight and obesity, as the study was designed to over-recruit ethnic and minority breast cancer survivors with a target goal of 30% minority participants. To support this diverse population, the weight loss intervention was designed to be delivered in both English and Spanish. The intervention workbook, calorie and fat gram counter, cookbook, and toolbox handouts are all available in English and Spanish. The study also employs bilingual coaches and call center staff, to ensure that participants are able to fully participate in the weight loss intervention in both languages. Spanish-speaking participants also receive one of a number of Spanish-language magazines as part of the health education program. The toolbox utilized to individualize the intervention was also designed to include a number of materials to allow for tailoring of the intervention to individuals of different cultures, such as sample menus that are tailored to Asian Indian, Caribbean-Latino, Mexican, and African American food. Additionally, a number of tailored strategies were developed to facilitate weight loss in diverse populations,

including: flexibility in scheduling calls to accommodate long work hours, visits back to home countries, and need to care for family members; simplified strategies such as focusing on smaller plates and portion sizes; MyPlate distribution of food groups tailored to cultural food staples; use and convenience of free meal replacement shakes for a meal on the go; and increasing “steps” rather than finding time for “workouts.” Study investigators also worked closely with the Alliance Health Disparities Committee to help support participating enrollment and engagement with the weight loss intervention. Finally, frequently asked question (FAQ) documents were developed in consultation with outside experts to address cultural issues that arise in the course of intervention delivery.

Training, Certification, and Treatment Fidelity in the Intervention

All coaches attend an initial, two-day training program to review implementation of the treatment protocol, followed by annual trainings that update coaches on study progress, new research relevant to the intervention, and motivational and behavioral techniques to facilitate case management. Members of the Lifestyle Intervention Committee (which developed the treatment protocol) participate in these trainings and provide expertise in oncology, nutrition, exercise physiology and behavioral sciences. The Behavioral Director of the call center (LMD), who has experience in the design and delivery of both DPP and Look AHEAD lifestyle interventions, provides more specific training on the effective delivery of each session, with specific guidance on strategies for tailoring the intervention to individual participant needs. Training tools include interactive techniques such as role plays, as well as a detailed, session-by-session coaches’ manual.

Coaches are certified to deliver the intervention prior to working with study participants. Certification requirements include: 1) learning the study protocol; 2) reviewing and demonstrating understanding of a frequently-asked-questions (FAQ) document that contains agreed-upon responses to common questions about the administrative, diet, physical activity, breast cancer treatment, and retention aspects of intervention delivery; and 3) successful completion of two role plays - of sessions 1 and 4, respectively - that demonstrate the coaches’ mastery of the content, process, and time constraints for delivering the sessions. Coaches must be re-certified annually by meeting content and process checklist requirements for treatment fidelity during the delivery of two recent sessions. Treatment fidelity is further monitored through review of at least 4 additional recorded calls per coach per year.

Lifestyle coaches receive ongoing training and support in weekly team meetings that focus on counseling strategies, motivational interviewing techniques, case discussions, review of responses to new FAQs that arise, and retention strategies. In addition, expert speakers are invited to address breast cancer specific topics and relevant psychological and behavioral issues. The lifestyle coaches represent a multi-disciplinary team, which includes registered dietitian-nutritionists, registered nurses, exercise physiologists/trainers, and social workers who can provide expertise. Most of the coaches had no prior experience in research or in delivering a lifestyle intervention, however every coach had some counseling experience in their area of expertise and several were multilingual.

Strategies to Promote Participant Engagement and Retention

Lifestyle intervention participants often experience barriers to session attendance, treatment adherence, and goal attainment which can adversely affect retention. Some of the common barriers include self-monitoring difficulties, social cues for unhealthy eating, competing priorities, major life events and stressors, negative thoughts and emotions, frustration with weight loss progress or the demands of the intervention, and concerns or ambivalence about study participation (76). Other barriers for BWEL participants are or may be related to breast cancer diagnosis and treatment. Some examples are anxiety, depression, and difficulties with side effects from medications, radiation and surgery (e.g., fatigue and lymphedema). The coaches receive guidance on how to help participants address these barriers and modify the intervention to meet the needs of the participant. For example, some participants, during high stress times or when recovering from reconstructive surgery, may need a short break from the intervention. Coaches receive suggestions for sample phrases or explanations to use on phone calls and guidelines for crafting tailored emails to address barriers and help maintain program engagement. Coaches are trained to normalize participants' frustrations with weight loss plateaus or weight regain, and to help women learn ways to stay motivated, reframe expectations, and focus on the benefits of participation, all of which help to maximize retention.

Conclusion

The BWEL trial tests the efficacy of weight loss through increased physical activity and diet / energy intake modification on invasive disease-free survival in women with early-stage breast cancer and overweight or obesity. Drawing upon prior successful interventions in weight management and promotion of healthy behaviors in cancer survivors, the BWEL lifestyle intervention was designed to have the greatest probability of achieving and maintaining a 7% or greater study-wide loss, achieved through standardized, remote delivery from a centralized call center. If the BWEL lifestyle intervention is successful in improving invasive disease-free recurrence, the intervention can be adapted for broader dissemination, ultimately informing standard breast cancer care.

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What is already known about this subject?

- Lifestyle interventions can result in clinically significant weight loss and improvement in cardiometabolic risk factors.
- The feasibility and benefits of weight loss interventions in cancer survivors with overweight and obesity have been demonstrated.

What are new findings in this manuscript?

- This report provides a detailed description of the goals and methods of the Breast Cancer Weight Loss (BWEL) trial lifestyle intervention.
- The evidence supporting the diet, physical activity and behavioral components of this telephone-based weight loss intervention as well as strategies to promote participant engagement and retention are described.

How might results change the direction of research or the focus of clinical practice?

- If the BWEL lifestyle intervention is successful in improving cancer outcomes, the intervention will likely have a major impact on future breast cancer treatment protocols and programs.
- If successful, this weight loss intervention could be adapted for broader dissemination and inform breast cancer care.

Table 1.

Comparison of Lifestyle Intervention Features of DPP, Look AHEAD, LISA, and BWEL

	DPP	Look AHEAD	LISA	BWEL
Weight loss goal	Study goal =7% Individual goal =7%	Study goal =7% Individual goal =10%	Study goal = up to 10% Individual goal = up to 10% based on BMI; for BMI 24-25, goal = prevent weight gain	Study goal =7% Individual goal =10%
Activity goal	≥ 150 min/wk	≥ 175 min/wk	150-200 min/wk	≥ 150 min/wk in first 6 mo; 225-300 min/wk in mo 6-24; reduce sedentary behavior; aim for 10, 000 steps per day by end of year 1
Dietary goals	Fat: < 25% of calories, saturated fat: < 10%	Fat: < 30% of calories, saturated fat: < 10%	Fat: 20% of calories, increased intake of fruits, vegetables, and whole grains	Fat: 20-35% of calories
Calorie and fat gram targets	1200 kcal, 33 g fat if 120-170 lbs 1500 kcal, 42 g fat if 175-215 lbs 1800 kcal, 50 g fat if 220-245 lbs 2000 kcal, 55 g fat if > 250 lbs	1200-1500 kcal and 40-50 g fat if < 250 lbs, 1500-1800 kcal and 50-60 g fat if > 250 lbs	1250 kcal 1500 kcal 1750 kcal 20% of kcal from fat	1200-1500 kcal and 30-60 g fat * if ≤ 250 lbs, 1500-1800 kcal and 30-70 g fat * if > 250 lbs
Nutrition intervention	Fat gram counting with addition of calorie counting as needed; self-selected diet	Calorie counting with fat gram goals; portion-controlled diet	Calorie counting with inclusion of fat gram goals	Calorie counting Counting fat gram intake for first few wks
Meal Replacements	Recommended as a tool box or campaign strategy	Recommended as a regular part of portion-controlled diet and campaigns	Not included	Recommended as a regular part of portion-controlled diet
Session format	Individual in-person sessions, also refresher groups and campaigns after the first 6 months	Group plus individual in the first year; individual with refresher groups and campaigns thereafter	Individual phone with paper workbook	Individual phone with online and paper workbook
Number of sessions	Minimum of 25 sessions plus 2 (4-to-6-week) refresher groups in 2 yrs	Minimum of 54 sessions plus 3 (6-to-8-week) refresher groups in 2 yrs	19 calls in 2 yrs	42 sessions in 2 yrs
Frequency of sessions	16 sessions in first 6 mo, minimum of 1 in-person session every 2 mo thereafter	24 sessions in first 6 mo, 18 sessions in mo 7- 12, monthly sessions in Yrs 2 and beyond	Weekly for 5 wks, biweekly in mo 2 and 3, monthly in mo 4-6, every 2 mo in mo 7-12, every 3 mo in Yr 2	Weekly for 12 wks, biweekly for the rest of Yr 1, monthly in Yr 2
Intervention duration	Average of 2.8 years	Median 9.6 years	2 years	2 years
Toolbox strategies	Used throughout the intervention based on identification of barriers to achieving activity and weight loss goals; problem solving strategies and no-cost items (reinforcers) used initially, higher-cost items after first 6 mo and only after no-cost or low-cost approaches had been tried	Used after the first 6 months if participants did not meet activity goal or lose 5% of initial weight or regained more than 2% from lowest weight; includes use of high-cost items, and weight loss medications	Use of problem solving and motivational strategies	Used throughout the intervention based on identification of barriers to achieving activity and weight loss goals

DPP (Diabetes Prevention Program); Look AHEAD (Action for Health in Diabetes); LISA (Lifestyle Intervention Study for Adjuvant Treatment of Early Breast Cancer); BWEL (Breast Cancer Weight Loss Trial)

* Participants received fat gram target ranges of 20-35% of calories from fat based on evidence that a variety of macronutrient levels can promote weight loss in the context of a calorie deficit

Table 2.

BWEL Session Topics by Week of Intervention

Week	Topics
1	Welcome to the Lifestyle Program
2	Getting Started: Tipping the Calorie Balance
3	Not All Fats Are Created Equal: Eat Less of Most, More of Some
4	Cutting Calories by Controlling Your Portions
5	Move Those Muscles
6	Working With What's Around You: Cue Control
7	Problem Solving
8	Being Active: A Way of Life
9	Healthy Eating
10	Healthy Eating and Breast Cancer
11	Four Keys to Healthy Eating Out
12	Summary and Progress Review of the First Three Months
14	Talk Back to Negative Thoughts
16	The Slippery Slope of Lifestyle Change
18	Supermarket Smarts
20	Emotions and You
22	Handling Holidays, Vacations, and Special Events
24	Taking Stock and Celebrating Your Success
26	Ramp Up Your Activity Plan
28	Make Social Cues Work for You
30	Ways to Stay Motivated
32	Ten Ways to Control Your Hunger
34	Build a Better Breakfast
36	Build a Better Lunch and Dinner
38	Build Better Snacks
40	Managing Stress and Eating Mindfully
42	Managing Your Time
44	Recovering from an Overeating Episode
46	Weight Loss Tune Up
48	Stepping Up Your Physical Activity
50	Summary and Review of Year 1
54	A New Balancing Act: Adjustments for Long-Term Success
58	Lessons from the Best Weight Losers and Maintainers
62	Getting Support for Being Active
66	Structured Meals for Keeping Off the Weight You Lose
70	Feeling Full on Fewer Calories
74	The Magic of Soups, Cooked Grains, and Legumes

Week	Topics
80	The Effect of Mood and Hunger on Your Eating and Activity
86	Staying Positive
92	Creating a Personal Comeback Plan
98	Preparing for What Comes Next
104	Graduation