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Impact of a Weight Loss Intervention on 1-Year Weight Change in Women With Stage II/III Breast Cancer

Secondary Analysis of the Breast Cancer Weight Loss (BWEL) Trial

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IMPORTANCE Obesity is associated with a higher risk of recurrence, mortality, comorbidities, treatment-related adverse effects, and poor quality of life in patients with breast cancer. Scalable interventions are needed to promote weight loss in this population.

OBJECTIVE To evaluate the impact of a remotely delivered weight loss intervention (WLI) on weight change at 1 year in patients with breast cancer and obesity and to explore factors associated with weight change.

DESIGN, SETTING, AND PARTICIPANTS The Breast Cancer Weight Loss trial is a phase 3, randomized clinical trial evaluating the impact of a telephone-based WLI on invasive disease–free survival and other outcomes in women with obesity and early breast cancer at 637 sites across the US and Canada. Participants were enrolled to the study between August 2016 and February 2021. Participants included women with stage II to III, *ERBB2*-negative breast cancer and a body mass index (BMI) of 27 or higher.

INTERVENTIONS Participants were randomized to a 2-year, telephone-based WLI plus health education or health education alone control group.

MAIN OUTCOME AND MEASURES The primary end point for this prespecified secondary analysis was weight change at 1 year. Weight was measured at baseline and 1 year, and changes in weight were compared between groups. Weight change was evaluated with a linear mixed-effects model including treatment group, weight over time, a time-by-group interaction, menopausal status, race and ethnicity, and hormone receptor status.

RESULTS A total of 3180 women with breast cancer and BMI of 27 and higher were included in the study; 1591 were randomized to the WLI and 1589 to the control group. At baseline, the mean (SD) age of participants was 53.4 (10.6), and the mean (SD) BMI was 34.4 (5.6). The racial and ethnic breakdown included 406 (12.8%) Black, 231 (7.3%) Hispanic or Latino, 2906 (91.4%) non-Hispanic, and 2555 (80.3%) White participants. WLI participants lost a mean of 4.3 kg (95% CI 3.9-4.6 kg), or 4.7% (95% CI, 4.3%-5.0%) of baseline body weight at 1 year vs control participants, who gained 0.9 kg (95% CI, 0.5-1.3 kg), or 1.0% (95% CI 0.1%-1.4%) of baseline body weight ($P < .001$). Participants randomized to WLI experienced significant weight loss (vs control group participants) across demographic and tumor factors. WLI effect differed significantly by menopausal status, with postmenopausal participants having greater weight loss than premenopausal participants, and by race and ethnicity, with Black and Hispanic participants having less weight loss compared to other races and ethnicities.

CONCLUSIONS AND RELEVANCE In this secondary analysis of a randomized clinical trial, a telephone-based WLI induced significant weight loss in patients with breast cancer with overweight and obesity across demographic and treatment factors. Further follow-up of the Breast Cancer Weight Loss trial will evaluate whether the WLI improves disease outcomes.

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Visual Abstract
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Supplemental content

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Individuals with obesity at the time of breast cancer diagnosis are at higher risk of recurrence, cancer-specific mortality, and all-cause mortality as compared with leaner individuals.[1-8] Obesity is also associated with increased risk of acute and long-term adverse effects of cancer treatment, including higher risk of lymphedema and other surgical complications,[9-11] complications of radiation therapy,[12-14] neuropathy,[15,16] cardiovascular toxic effects,[17] comorbidities, and fatigue.[18] These factors contribute to increased risk of poor quality of life following breast cancer diagnosis in patients with obesity.[15,19]

A number of studies have evaluated the feasibility and benefits of weight loss interventions (WLIs) in patients with breast cancer, demonstrating that weight loss is feasible in this population and leads to improvements in quality of life and other patient-reported outcomes.[20-25] However, most studies to date have been small, have primarily enrolled non-Hispanic White patients with breast cancer, and have tested in-person, group-based interventions that are difficult to disseminate across the dispersed settings in which patients with breast cancer are treated. Additional work is needed to test the efficacy and benefits of scalable WLIs in diverse populations of breast cancer survivors.

The Breast Cancer Weight Loss (BWEL) trial (Alliance for Clinical Trials in Oncology A011401) is a phase 3 trial designed to evaluate the impact of a WLI on cancer outcomes in a diverse group of 3180 women with a body mass index (BMI) of 27 or higher (calculated as weight in kilograms divided by height in meters squared) diagnosed with stage II to III *ERBB2*-negative breast cancer.[26] In this secondary analysis of the BWEL randomized clinical trial, we describe the impact of the WLI on weight change at 1 year in BWEL and explore factors associated with weight change.

Key Points

Question Can a remotely delivered weight loss intervention (WLI) reduce weight in a diverse population of women with breast cancer and a body mass index of 27 or higher?

Findings In this secondary analysis of a randomized clinical trial involving 3180 women with breast cancer, participants randomized to the WLI lost a mean of 4.3 kg, or 4.7% of their baseline body weight, at 1 year, compared to control group participants who gained an average of 0.9 kg, or 1.0% of their baseline body weight. Participants randomized to the WLI experienced significant weight loss (vs control group participants) across demographic, tumor, and treatment factors.

Meaning The WLI led to statistically significant and clinically meaningful weight loss in patients with breast cancer with overweight and obesity across demographic and treatment factors.

Methods

Study Design and Participants

Detailed descriptions of the BWEL randomized clinical trial design[26] and WLI have previously been published.[27] In brief, the BWEL trial tests the impact of a 2-year, telephone-based WLI plus health education materials (vs health education materials alone) on invasive disease-free survival in women with stage II to III breast cancer and a BMI of 27 or higher. (See Supplement 1 for the trial protocol.) We present the prespecified secondary objective evaluating the impact of the WLI (vs control) on weight change at 1 year. This study was approved by the National Cancer Institute Adult Central Institutional Review Board–Late Emphasis Panel. Informed consent was obtained from all participants prior to enrollment. Enrollment occurred between August 2016 and February 2021. All research was conducted in accordance with the US Common Rule. This study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.

Participants were recruited from 637 sites across the US and Canada. Key eligibility criteria included diagnosis of stage II to III, *ERBB2* negative breast cancer within the past 16 months, BMI of 27 or higher, female sex, ability to speak and read English or Spanish, and completion of surgery and any chemotherapy or radiation therapy at least 21 days prior to enrollment. Patients with diabetes treated with insulin or sulfonylurea drugs, and patients taking any drug for the purpose of weight loss or who planned to undergo bariatric surgery within 2 years, were not eligible.

WLI

The development and design of the WLI have been described in detail.[27] Participants randomized to the WLI group received a 2-year, telephone-based, lifestyle intervention that promoted weight loss through caloric restriction and increased physical activity (eTable 1 in Supplement 2). The WLI was based on social cognitive theory and focused on building knowledge, self-monitoring, goal setting, problem solving, and stimulus control.[28] Participants worked individually with health coaches based at a call center at the Dana-Farber Cancer Institute. Calls, delivered in English or Spanish, were conducted weekly for the first 12 weeks and biweekly through month 12.

The WLI was designed to induce an energy deficit of 500 to 1000 kcal/d to promote weight loss of 0.5 to 1.0 kg per week (1 to 2 lb per week).[27] Participants were given an initial target calorie range, based on baseline body weight (1200-1500 kcal/d for participants weighing ≤113.6 kg and 1500-1800 kcal/d for those weighing >113.6 kg). Calorie goals were subsequently modified based on the rate of weight loss achieved. Exercise goals were 150 minutes per week of moderate or vigorous recreational physical activity for the first 6 months of the study and then increased to 225 minutes per week in months 6 to 12.

Participants received a workbook and tools, including an activity monitor (Fitbit, Inc) and meal replacement shakes (Nestle Health Sciences), to help optimize weight loss. A toolbox, including alternative dietary plans (eg, vegetarian, low carbohydrate, gluten free) and recipes (eg, Caribbean, Mexican, South Indian), was used to tailor the intervention to meet the needs of a diverse patient population.[26,27]

Health Education Program

All participants received a health education program that provided nontailored information about healthy diet and exercise. The program included quarterly study newsletters, twice-yearly webinars, biannual mailings of educational materials and

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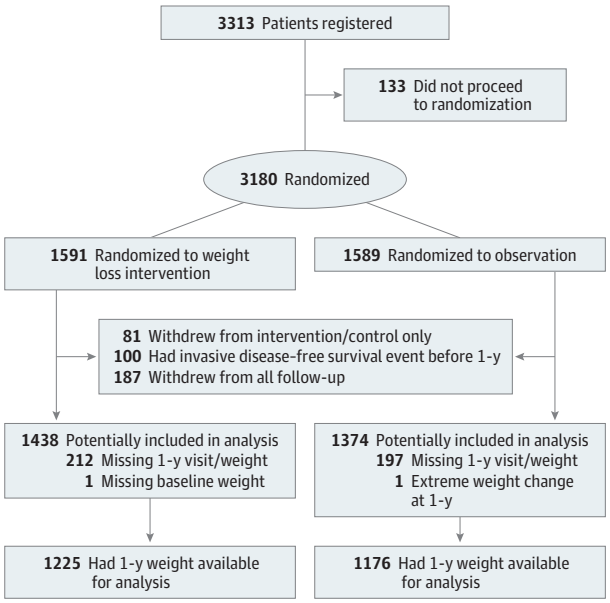
Figure 1. Consort Diagram



study-themed gifts (eg, a water bottle and hat), annual holiday and anniversary cards, and a 2-year subscription to a health-related magazine of the participant's choice.

Outcome Measures

Self-reported demographic information was collected by questionnaire at baseline. Menopausal status was defined based on the frequency of menstrual cycles in the year prior to breast cancer diagnosis. Participants who had not had a menstrual cycle within 1 year of cancer diagnosis, those who had bilateral oophorectomy, and those who had a hysterectomy and were younger than 55 years were considered postmenopausal. All other participants were considered premenopausal or perimenopausal. Race and ethnicity were self-identified. Stratification was based on a 3-level race and ethnicity factor by which patients self-categorized at the time of enrollment as Black, Hispanic or Latino, or other to ensure even distribution of races and ethnicities across treatment arms. Participants who self-identified as both Black and Hispanic or Latino were categorized for stratification purposes as Black. Participants additionally provided more detailed information about race and ethnicity on the baseline participant questionnaire after enrollment to provide a more complete summary of the racial and ethnic information of study participants (eTable 2 in Supplement 2). Disease and treatment information were abstracted from the medical record.

Height and weight were collected by study staff in duplicate, with participants wearing light indoor clothing and without shoes, at baseline. Weight was collected using this method every 6 months for the first 3 years and then annually. Height and weight were used to calculate BMI.

The Alliance for Clinical Trials in Oncology issued a memorandum in March 2020 allowing virtual follow-up visits during the COVID-19 pandemic. Virtual visits were incorporated

Table 1. Baseline Characteristics

Characteristic	No. (%) Control (n = 1589)	WLI (n = 1591)	Total (N = 3180)
Age, y			
Mean (SD)	53.2 (10.6)	53.6 (10.6)	53.4 (10.6)
Median (range)	53.0 (22.0-82.0)	54.0 (25.0-82.0)	53.0 (22.0-82.0)
Time from diagnosis date to enrollment, mo			
Mean (SD)	10.2 (2.3)	10.1 (2.4)	10.1 (2.3)
Median (range)	10.6 (0-17.6)	10.6 (0-23.2)	10.6 (0-23.2)
Missing, No.	7	12	19
Menopausal status			
Postmenopausal	908 (57.1)	912 (57.3)	1820 (57.2)
Premenopausal	681 (42.9)	679 (42.7)	1360 (42.8)
BMI at randomization			
Mean (SD)	34.3 (5.6)	34.5 (5.7)	34.4 (5.6)
Median (range)	33.2 (22.7-61.1)	33.2 (26.6-69.1)	33.2 (22.7-69.1)
Missing, No.	1	1	2
BMI category			
Overweight (27 to <30)	375 (23.6)	386 (24.3)	761 (23.9)
Obese (≥30)	1213 (76.4)	1204 (75.7)	2417 (76.1)
Missing, No.	1	1	2
Hormone receptor status			
ER and PR negative	325 (20.5)	325 (20.4)	650 (20.4)
ER and/or PR positive	1264 (79.5)	1266 (79.6)	2530 (79.6)
Stratification factor: race and ethnicity[a]			
Black	201 (12.6)	200 (12.6)	401 (12.6)
Hispanic or Latino	113 (7.1)	113 (7.1)	226 (7.1)
Other	1275 (80.2)	1277 (80.3)	2552 (80.3)
Missing, No.	0	1	1
Race[b]			
American Indian or Alaska Native	4 (0.3)	7 (0.4)	11 (0.3)
Asian	34 (2.1)	35 (2.2)	69 (2.2)
Black	202 (12.7)	204 (12.8)	406 (12.8)
Native Hawaiian or Pacific Islander	6 (0.4)	1 (0.1)	7 (0.2)
White	1274 (80.2)	1281 (80.5)	2555 (80.3)
Multiracial	9 (0.6)	7 (0.4)	16 (0.5)
Unknown	60 (3.8)	56 (3.5)	116 (3.6)
Ethnicity[b]			
Hispanic or Latino	118 (7.4)	113 (7.1)	231 (7.3)
Not Hispanic or Latino	1447 (91.1)	1459 (91.7)	2906 (91.4)
Unknown	24 (1.5)	19 (1.2)	43 (1.4)
T stage			
T0-T1	438 (27.6)	470 (29.6)	908 (28.6)
T2	824 (51.9)	812 (51.1)	1636 (51.5)
T3-T4	316 (19.9)	293 (18.4)	609 (19.2)
TX	10 (0.6)	15 (0.9)	25 (0.8)
Missing, No.	1	1	2
N stage			
N0	291 (18.3)	295 (18.6)	586 (18.4)
N1-N3	1272 (80.1)	1275 (80.2)	2547 (80.1)
NX	25 (1.6)	20 (1.3)	45 (1.4)
Missing, No.	1	1	2
Surgery type			
Partial mastectomy	838 (52.7)	865 (54.4)	1703 (53.6)
Mastectomy	732 (46.1)	705 (44.3)	1437 (45.2)
Unknown	19 (1.2)	21 (1.3)	40 (1.3)

(continued)

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Table 1. Baseline Characteristics (continued)

Characteristic	No. (%) Control (n = 1589)	WLI (n = 1591)	Total (N = 3180)
Received adjuvant or neoadjuvant chemotherapy	1289 (81.4)	1288 (81.1)	2577 (81.2)
Received adjuvant or neoadjuvant endocrine therapy	1197 (75.3)	1189 (74.7)	2386 (75.0)
Endocrine therapy type			
Aromatase inhibitor	796 (67.6)	820 (69.7)	1616 (68.6)
Tamoxifen	322 (27.3)	313 (26.6)	635 (27.0)
Both aromatase inhibitor + tamoxifen	59 (5.0)	41 (3.5)	100 (4.2)
Ovarian function suppression[c]	169 (14.2)	189 (15.9)	358 (15.1)
Other	1 (0.1)	3 (0.3)	4 (0.2)
Missing, No.	19	12	31
Underwent radiation therapy	1381 (86.9)	1419 (89.2)	2800 (88.1)
Combined household income			
<$50 000	384 (28.6)	412 (30.2)	796 (29.4)
$50 000 to $119 999	579 (43.0)	599 (43.9)	1178 (43.5)
≥$120 000	382 (28.4)	354 (25.9)	736 (27.2)
Missing, No.	244	226	470
Education			
<College graduate	681 (43.3)	654 (41.6)	1335 (42.4)
College graduate	479 (30.5)	484 (30.7)	963 (30.6)
Postgraduate education or degree	411 (26.2)	436 (27.7)	847 (26.9)
Missing, No.	18	17	35
Geographic region			
Canada	106 (6.7)	108 (6.8)	214 (6.7)
US Midwest	471 (29.6)	493 (31.0)	964 (30.3)
US Northeast	346 (21.8)	345 (21.7)	691 (21.7)
US South	404 (25.4)	385 (24.2)	789 (24.8)
US West	262 (16.5)	260 (16.3)	522 (16.4)
Smoking status			
Never smoker	1030 (64.8)	1023 (64.3)	2053 (64.6)
Former smoker	477 (30.0)	507 (31.9)	984 (30.9)
Current smoker	73 (4.6)	54 (3.4)	127 (4.0)
Current or former smoker (incomplete information)	9 (0.6)	7 (0.4)	16 (0.5)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); ER, estrogen receptor; PR, progesterone receptor; WLI, weight loss intervention.

[a] Stratification was based on a 3-level self-identified race and ethnicity factor by which patients were categorized as Black, Hispanic or Latino, or other (another race or ethnicity). If a patient self-identified as both Black and Hispanic or Latino, they were categorized for stratification purposes as Black.

[b] Participants completed a baseline questionnaire with more detailed information regarding race and ethnicity after study enrollment.

[c] Patients underwent ovarian suppression in addition to other forms of endocrine therapy, so percentages do not amount to 100%.

into the BWEL protocol through an amendment in August 2022. Weight was recorded as missing for all virtual visits.

Statistical Analysis

Weight change between the WLI and control groups at 1 year was a prespecified secondary end point of the BWEL trial, with an interim analysis mandating a between-group difference of at least 4% of baseline body weight planned when 25% of the study population reached the 1-year time point. The study passed the interim analysis in May 2019. Once the entire study population completed the 24-month intervention period, the Alliance Data and Safety Monitoring Board approved the release of 1-year weight data for analysis and publication.

The primary end point for this prespecified secondary analysis was weight change at 1 year. For the primary analysis, weight change was evaluated using a linear mixed model that contained weights at baseline, 6 months, and 1 year, treatment group, time-by-group interaction term, and covariables (menopausal status, baseline BMI, hormone receptor [HR] status, race and ethnicity, education level, income level, and smoking status). Point estimates and 95% CIs of the weights by treatment group and time point were calculated. Mean weight change (and mean change percentage) was also estimated for each group (WLI and control) with a point estimate and corresponding paired *t* test 95% CI. Similarly, point estimates and corresponding paired *t* test 95% CI of mean weight change percentage were generated for each intervention by subgroups. The mean difference in weight change (or weight change percentage) between the WLI and control groups was examined using a *t* test, and *P* values were computed both overall and by subgroups. Point estimates were computed with corresponding paired *t* test 95% CIs. An additional evaluation for differential intervention (WLI vs control) effects on the weight change percentage among groups was determined with a multiple regression model that included the variable of interest, intervention group, the variable by intervention interaction term, and covariables (menopausal status, baseline BMI, HR status, race and ethnicity, education level, income level, and smoking status).

Analyses were performed with SAS, version 9.4 (SAS Institute), and R, version 4.3.1 (R Project for Statistical Computing), statistical software. A 2-sided $P < .05$ level of significance was used. The database for this analysis was frozen on March 5, 2024. Data collection and statistical analyses were conducted by the Alliance Statistics and Data Management Center. Data quality was ensured by review of data by the Alliance Statistics and Data Management Center and by the study chairperson following Alliance policies. This trial was monitored at least twice annually by the Alliance Data and Safety Monitoring Board, a standing committee composed of individuals from within and outside of the Alliance.

Results

Patient and Treatment Characteristics

A total of 3180 patients were enrolled in the BWEL trial with 1591 randomized to the WLI and 1589 to the control group (**Figure 1**). There were no meaningful differences in baseline characteristics between the groups (**Table 1**). Mean (SD) age was 53.4 (10.6) years; mean (SD) BMI at baseline was 34.4 (5.6). Overall, 406 participants (12.8%) were Black, 231 (7.3%) were Hispanic or Latino, 2906 (91.4%) were non-Hispanic, and 2555 (80.3%) were White. Overall, 2577 participants (81.2%) had received neoadjuvant or adjuvant chemotherapy, 2800 (88.1%) had undergone radiation therapy, and 2386 of 2530 participants with HR-positive cancers (94.3%) received endocrine therapy.

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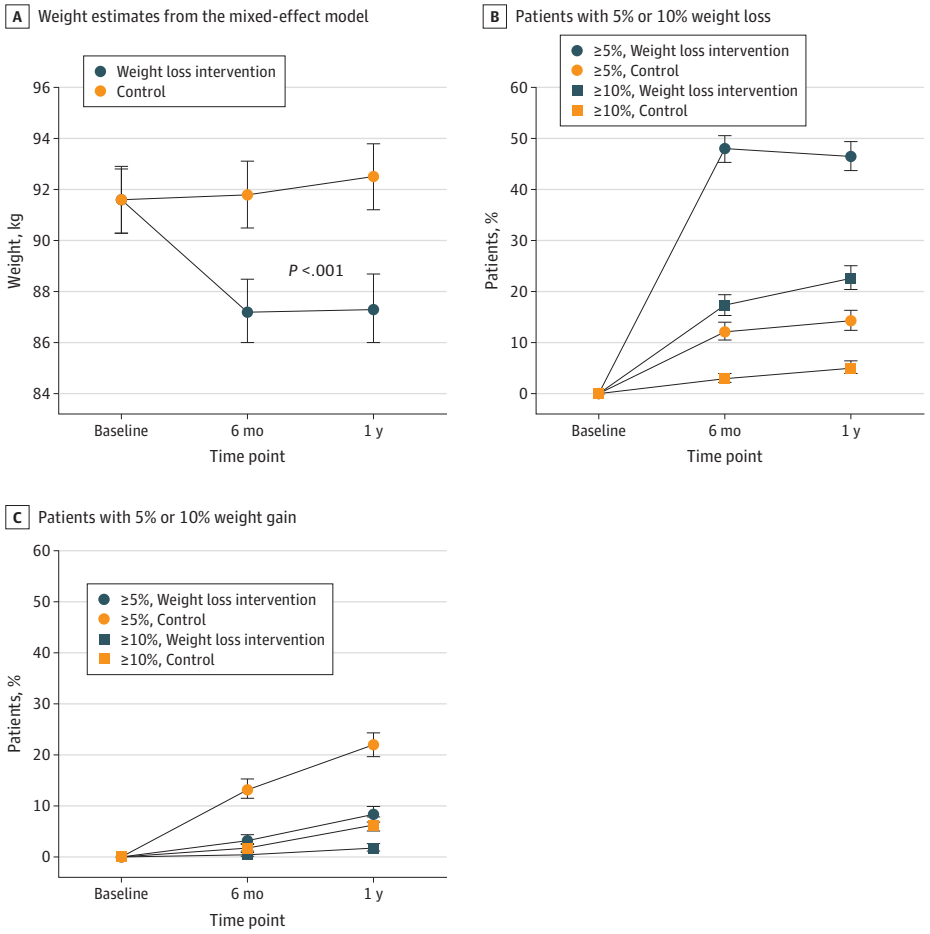
Figure 2. Weight Loss Outcomes at Baseline, 6 Months, and 1 Year by Study Group



The points indicate mean values, and whiskers indicate 95% CIs. The *P* values compared weight outcomes between the weight loss intervention and control groups over time using the mixed-effect model.

Weight Change at 6 Months and 1 Year

Between baseline and 1 year, 187 participants (5.9%) withdrew from all follow-up, 81 (2.5%) withdrew from the intervention/control only, and 100 (3.1%) experienced an invasive disease-free survival event (Figure 1). In the WLI group, weights at 6 months and 1 year were available for 1366 participants (85.9%) and 1225 participants (77.0%), respectively. In the control group, weights at 6 months and 1 year were available from 1318 (82.9%) and 1176 (74.0%), respectively. Approximately 47% of missing weights would have been collected during the first 18 months of the COVID-19 pandemic. Individuals missing 1-year weight (vs those with weight available) were more likely to have HR-negative tumors (158 of 679 [23.3%] vs 453 of 2401 [18.9%], respectively; $P = .01$), to be Black (114 of 679 [16.8%] vs 271 of 2401 [11.3%], respectively; $P = .001$), and to have an annual household income of less than $50 000 (186 of 679 [33.8%] vs 573 of 2401 [27.7%], respectively; $P = .01$; eTable 3 in Supplement 2). There were no significant differences in baseline characteristics between the intervention and control groups in the participants for whom 1-year weights were available (eTable 4 in Supplement 2).

Mean weight at baseline was similar in the WLI group (91.6 kg [95% CI, 90.3-92.8 kg]) and control group (91.6 kg [95% CI, 90.3-92.9 kg]) (eTable 5 in Supplement 2). At 6 months, mean weight in control participants was 91.8 kg (95% CI, 90.5-93.1 kg) vs 87.2 kg (95% CI, 86.0-88.5 kg) in the WLI group. At 1 year, mean weight in control participants was 92.5 kg (95% CI, 91.2-93.8 kg) vs 87.3 kg (95% CI, 86.0-88.7 kg) in the WLI group. Using a linear mixed model containing treatment group and a time-by-group interaction term, which was adjusted for covariables (menopausal status, baseline BMI, HR status, race and ethnicity, education level, income level, and smoking status), WLI participants lost a mean of 4.3 kg (95% CI, 3.9-4.6 kg) or 4.7% (95% CI, 4.3%-5.0%) of baseline body weight at 1 year, while control participants gained a mean of 0.9 kg (95% CI, 0.5-1.3 kg), or 1.0% (95% CI 0.1%-1.4%) of baseline body weight. The mean between-group difference in weight change at 1 year was 5.3 kg (95% CI, 3.9-6.5 kg) ($P < .001$; eTable 5 in Supplement 2; **Figure 2**A).

At 1 year, 569 WLI participants (46.5%) vs 168 control participants (14.3%) lost 5% of baseline body weight ($P < .001$), and 276 WLI participants (22.5%) lost 10% of baseline body weight vs 59 control participants (5.0%; $P < .001$; Figure 2B). Conversely, at 1 year, 258 control participants (21.9%) gained more than 5% of baseline body weight, vs 101 WLI participants (8.2%; Figure 2C).

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Table 2. Mean Percentage Weight Change Between Baseline, 6 Months, and 1 Year by Patient, Tumor, and Treatment Factors

Variable	Mean percentage weight change (95% CI), %			
	6 mo vs Baseline		1 y vs Baseline	
	Control	WLI	Control	WLI
No.	1318	1368	1176	1225
Overall	0.29 (0.02 to 0.57)	−4.74 (−5.04 to −4.43)	0.87 (0.51 to 1.23)	−4.83 (−5.26 to −4.39)
P value for group comparison[a]	<.001		<.001	
Menopausal status				
Premenopausal	0.32 (−0.08 to 0.73)	−4.0 (−4.4 to −3.5)	1.36 (0.79 to 1.93)	−3.96 (−4.43 to −3.50)
Postmenopausal	0.26 (−0.11 to 0.64)	−5.31 (−5.71 to −4.91)	0.50 (0.03 to 0.97)	−5.87 (−6.45 to −5.29)
BMI category				
Overweight (27 to <30)	0.06 (−0.01 to 1.21)	−5.07 (−5.68 to −4.46)	1.30 (0.57 to 2.03)	−5.23 (−6.12 to −4.35)
Obese (≥30)	0.18 (−0.12 to 0.49)	−4.63 (−4.98 to −4.28)	0.72 (0.31 to 1.14)	−4.70 (−5.20 to −4.20)
HR status				
HR negative	0.73 (0.11 to 1.36)	−3.65 (−4.31 to −2.98)	1.04 (0.15 to 1.93)	−3.71 (−4.67 to −2.75)
HR positive	0.18 (−0.13 to 0.49)	−5.01 (−5.35 to −4.69)	0.82 (0.43 to 1.23)	−5.09 (−5.58 to −4.61)
Race and ethnicity[b]				
Black	1.17 (0.50 to 1.84)	−1.93 (−2.75 to −1.10)	2.13 (1.11 to 3.14)	−1.61 (−2.80 to −0.43)
Hispanic or Latino	0.57 (−0.46 to 1.59)	−2.92 (−3.85 to −1.98)	0.98 (−0.47 to 2.44)	−3.16 (−4.47 to −1.84)
Other	0.14 (−0.17 to 0.44)	−5.30 (−5.64 to −4.96)	0.69 (0.28 to 1.08)	−5.43 (−5.92 to −4.94)
Education				
<College graduate	0.22 (−0.20 to 0.63)	−4.37 (−4.88 to −3.87)	1.18 (0.60 to 1.77)	−4.56 (−5.24 to −3.89)
College graduate	0.63 (0.17 to 1.09)	−5.07 (−5.63 to −4.51)	1.14 (0.53 to 1.75)	−5.24 (−6.06 to −4.43)
Postgraduate education or degree	−0.02 (−0.61 to 0.60)	−4.90 (−5.42 to −4.37)	0.09 (−0.60 to 0.78)	−4.81 (−5.62 to −4.00)
Income				
<$50 000	0.39 (−0.19 to 0.96)	−3.92 (−4.52 to −3.32)	1.69 (0.97 to 2.42)	−4.46 (−5.33 to −3.57)
$50 000 to $120 000	0.33 (−0.16 to 0.82)	−5.11 (−5.57 to −4.64)	0.84 (0.22 to 1.46)	−4.83 (−5.49 to −4.16)
>$120 000	0.16 (−0.33 to 0.67)	−4.97 (−5.64 to −4.30)	0.39 (−0.30 to 1.09)	−5.00 (−5.93 to −4.07)
Received neoadjuvant or adjuvant chemotherapy				
Yes	0.52 (0.21 to 0.83)	−4.51 (−4.85 to −4.17)	1.13 (0.72 to 1.55)	−4.41 (−4.89 to −3.94)
No	−0.74 (−1.30 to −0.17)	−5.77 (−6.45 to −5.08)	−0.27 (−0.99 to 0.45)	−6.68 (−7.71 to −5.65)
Received neoadjuvant or adjuvant endocrine therapy (only HR-positive disease)				
Yes	0.16 (−0.15 to 0.48)	−5.00 (−5.35 to −4.65)	0.79 (0.38 to 1.20)	−5.08 (−5.58 to −4.58)
No	0.49 (−0.70 to 1.68)	−5.17 (−6.56 to −3.78)	1.55 (−0.29 to 3.40)	−5.28 (−7.44 to −3.13)
Smoking status				
Never	0.43 (0.08 to 0.78)	−4.76 (−5.15 to −4.37)	0.93 (0.50 to 1.37)	−4.86 (−5.41 to −4.31)
Former	0.11 (−0.35 to 0.56)	−4.80 (−5.31 to −4.30)	0.79 (0.12 to 1.46)	−4.81 (−5.53 to −4.09)
Current	−0.47 (−2.01 to 1.07)	−4.06 (−6.25 to −1.86)	0.34 (−2.60 to 3.29)	−4.30 (−8.11 to −0.49)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); HR, hormone receptor; WLI, weight loss intervention.

[a] Two-group *t* test.

[b] Stratification was based on a 3-level self-identified race and ethnicity factor by which patients were categorized as Black, Hispanic or Latino, or other (another race or ethnicity). If patients self-identified as both Black and Hispanic or Latino, they were categorized for stratification purposes as Black.

Effect of WLI on Weight Loss by Demographic and Treatment Factors

WLI participants lost significantly more weight at 1 year than participants randomized to the control group across subgroups defined by patient and treatment factors in unadjusted analyses (**Table 2; Figure 3**) and in analyses adjusted for covariables (menopausal status, baseline BMI, HR status, race and ethnicity, education level, income level, and smoking

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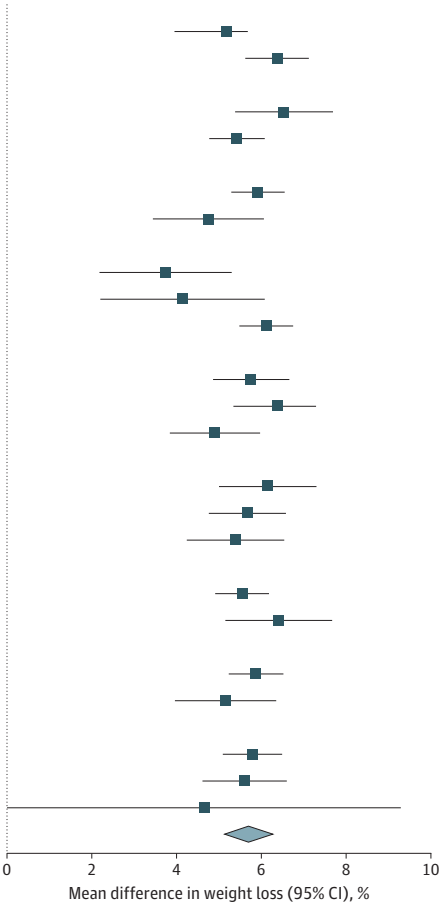
Figure 3. One-Year Weight Loss by Key Patient and Treatment Factors

Variable	Mean difference in weight loss (95% CI), %
Menopausal status	
Premenopausal	4.82 (3.95 to 5.68)
Postmenopausal	6.37 (5.62 to 7.12)
BMI category	
Overweight	6.53 (5.38 to 7.69)
Obese	5.42 (4.77 to 6.08)
ER/PR status	
ER and/or PR positive	5.92 (5.29 to 6.55)
ER and PR negative	4.75 (3.44 to 6.06)
Race and ethnicity	
African American	3.74 (2.18 to 5.30)
Hispanic or Latino	4.14 (2.20 to 6.08)
Other race and ethnicity[a]	6.11 (5.48 to 6.75)
Education	
<College	5.75 (4.86 to 6.64)
College	6.38 (5.34 to 7.42)
>College	4.90 (3.84 to 5.97)
Income, $	
<50 000	6.15 (5.00 to 7.30)
50 000-120 000	5.67 (4.76 to 6.58)
>120 000	5.39 (4.24 to 6.54)
Any chemotherapy	
Yes	5.55 (4.91 to 6.18)
No	6.41 (5.15 to 7.67)
Any endocrine therapy	
Yes	5.87 (5.23 to 6.52)
No[b]	5.16 (3.96 to 6.35)
Smoking status	
Never	5.79 (5.09 to 6.49)
Former	5.60 (4.61 to 6.60)
Current	4.64 (-0.003 to 9.29)
Overall	5.69 (5.13 to 6.27)



The mean percentage difference in weight loss is presented for each variable with whiskers indicating 95% CIs. BMI indicates body mass index; ER, estrogen receptor; PR, progesterone receptor.

[a]Stratification was based on a 3-level self-identified race and ethnicity factor by which patients were categorized as Black, Hispanic or Latino, or other (another race or ethnicity). If a patient self-identified as both Black and Hispanic or Latino, they were categorized for stratification purposes as Black.

[b]Hormone receptor–negative disease included in the "No" group.

status; eTable 6 in Supplement 2). Absolute differences in mean weight loss percentage between the WLI and control groups varied from 3.7% (95% CI, 2.2%-5.3%) to 6.8% (95% CI, 5.4%-7.7%) of baseline body weight (Table 2; eTable 7 in Supplement 2). The WLI effect differed by menopausal status and by race and ethnicity, with less weight loss in premenopausal participants and in Black and Hispanic or Latino participants (Figure 3; Table 2; eTables 6 and 7 in Supplement 2). There were no significant differences in the WLI effectiveness by tumor HR status, patient factors (education level, baseline BMI category, income level, smoking status), or treatment factors (receipt of chemotherapy or hormonal therapy).

WLI Adherence

Participants randomized to the WLI participated in a median of 26 of 30 planned calls (range, 1-34) during the first year of the WLI program (eTable 8 in Supplement 2). Weight loss correlated with number of calls (r^2 = 0.57; P = .02). Premenopausal WLI participants, participated in fewer calls than postmenopausal WLI participants (median, 25 calls [range, 1-34] vs 26 calls [range, 1-33]; P < .001), and Black and Hispanic or Latino WLI participants participated in fewer calls than those of other races and ethnicities (median for Black participants, 23 calls [range, 1-33]; median for Hispanic or Latino participants, 22 calls [range, 1-33], median for persons of other races and ethnicities, 26 calls [range, 1-34]; P < .001).

Discussion

In BWEL, a large phase 3 randomized clinical trial, a telephone-based WLI led to clinically significant weight loss in women with breast cancer and overweight or obesity. The trial enrolled patients from more than 600 academic and community oncology practices across the US and Canada. The intervention induced significant weight loss vs control across participant subgroups defined by patient and treatment-related factors, including in patient groups demonstrated to experience less weight loss in other studies. There were differential intervention effects by menopausal status and race, but weight loss did not differ significantly by education level, socioeconomic factors, or treatment factors, including receipt of chemotherapy and hormonal therapy. BWEL participants randomized to the health education control group gained an average of 1.0% of baseline body weight at 1 year, highlighting the significant challenges that patients with breast cancer

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experience in avoiding weight gain and the need for scalable WLIs that can be applied across clinical settings.

Weight loss achieved in our study is similar to that seen in other lifestyle-based weight loss studies in women, including those conducted using more intensive, in-person interventions.[29,30] The Diabetes Prevention Program demonstrated that an in-person, group-based WLI led to an average 6.9% weight loss at 6 months in individuals with insulin resistance.[20,21,29] Notably, fewer women than men (approximately 35% vs 55%) met the 7% weight loss goal. Similarly, the Exercise and Nutrition to Enhance Recovery and Good Health for You (ENERGY) trial demonstrated that an in-person, group-based WLI (vs a less-intensive control intervention) led to a loss of 6.0% of baseline body weight at 1 year (vs 1.5% loss in control group participants).[21] BWEL's success in achieving similar weight loss as seen in these studies, across a large study population and through a remotely delivered WLI, demonstrates the feasibility of widespread implementation of weight loss as a treatment strategy in early breast cancer.

In the BWEL trial, significant weight loss at 1 year was seen across subgroups defined by demographic and treatment factors, but less weight loss was seen in premenopausal participants and Black and Hispanic or Latino participants. These findings are similar to other studies[21]; in the Diabetes Prevention Program, for example, weight loss was less significant in individuals younger than 45 years, as well as in Black and Hispanic or Latino participants, as compared to participants who were 65 years and older or White, respectively.[29] In the ENERGY trial, women younger than 45 years had a mean weight loss of 0% at 24 months vs 5.2% in women 55 years and older, and Black participants lost 1.3% of baseline body weight at 2 years, as compared with 4.0% in non-Hispanic White participants, highlighting the difficulties of achieving significant weight loss in these patient populations.[21] More work is needed to identify effective interventions to induce weight loss in younger and in racial and ethnic minority breast cancer survivors.

Limitations

Our study has a number of limitations. More than 20% of study participants had missing weight data at 1 year, in part due to the shift to virtual visits during the COVID-19 pandemic. The population with missing weight at 1 year was slightly younger and more likely to be Black, to have HR-negative cancer, and to report a lower level of household income, resulting in potential bias given that these groups experienced less weight loss. Weight was also not collected in participants who experienced an invasive disease-free survival event, precluding intention-to-treat analysis. The weight loss we reported was relatively short-term and was collected while participants were still receiving regular coaching calls. Additionally, although we report data regarding the relationship between coaching calls received and weight loss, collection of detailed diet and exercise data was limited to a subset of BWEL participants enrolled in a prespecified substudy. Future analyses will evaluate the relationships among lifestyle changes, weight loss, and breast cancer outcomes in this cohort, but it will not be possible to evaluate the relationship between changes in dietary intakes and physical activity and weight loss outcomes across the BWEL study population. Finally, although the weight loss seen in the BWEL trial was statistically significant and was consistent with weight changes imparting favorable clinical effects on metabolic and cardiovascular end points,[21,31,32] weight loss was modest in comparison to that seen with pharmacologic and surgical WLIs. Further follow-up is needed to determine whether weight loss of this level impacts breast cancer outcomes and to evaluate the cost-effectiveness of behaviorally based WLIs vs pharmacologic and surgical approaches.

Conclusions

The BWEL trial is the first large-scale randomized clinical trial to successfully demonstrate the ability of a remotely delivered WLI to induce weight loss in a large, diverse population of breast cancer survivors. The data from this prespecified secondary analysis demonstrate the feasibility of implementing a lifestyle-based WLI as a part of breast cancer treatment. The BWEL trial provides a model for a centrally delivered WLI that is protocolized, ensuring consistent delivery, yet also designed for individualization through the use of toolbox strategies. Given the many adverse effects of obesity in patients with breast and other cancers, the BWEL trial provides a path to reduce toxic effects, reduce the risk of comorbidities such as diabetes and cardiovascular disease, and improve quality of life in the growing population of patients with cancer and obesity. Further, these findings suggest that the BWEL trial is poised to test the impact of lifestyle-based weight loss on disease outcomes in early breast cancer, potentially helping to mitigate the poor breast cancer outcomes experienced by women with obesity.

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