

Effect of a weight loss intervention (WLI) on quality of life (QOL) and symptoms in women with breast cancer: Results from the Breast Cancer Weight Loss (BWEL) trial.

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Background: BWEL (Alliance A011401; NCT02750826) is a Phase III trial that randomizes patients (pts) with stage II-III breast cancer and body mass index (BMI) ≥ 27 kg/m² 1:1 to a 24-month (mo) lifestyle-based WLI + health education (HE) or HE alone. Here we report prespecified secondary outcomes of the impact of the WLI on patient-reported QOL and symptoms. **Methods:** The first 540 BWEL pts (randomized between 9/2016 and 7/2017) were included in this substudy that collected PROMIS 29 Profile 2.0 and Global Health scores at enrollment, 6 and 24 mos. Adjusting for baseline scores, mean physical function (predefined substudy primary outcome), global physical and mental health, fatigue and other scores were compared at 6 and 24 mos using analysis of covariance (ANCOVA). P-values < 0.05 were considered significant. Positive differences in positive attributes (e.g., physical function) and negative differences in negative attributes (e.g., anxiety) represented better outcomes in the WLI arm. **Results:** At baseline, median BMI was 32.9 kg/m² (26.5 – 69.1), median age was 53 (25 – 78) years; 83.9% of pts were non-Hispanic White, 10.7% were Black and 5.9% were Hispanic. At 6 mos, the WLI (vs HE) arm had significantly better physical function (ANCOVA-based mean difference between arms 1.9 [95% CI 0.8, 3.0]; $p < 0.001$), global physical health (2.0 [95% CI 0.9, 3.0]; $p < 0.001$), global mental health (1.30 [95% CI 0.2, 2.4], $p = 0.03$), social roles and activities (2.3 [95% CI 1.1, 3.6]; $p < 0.001$), and fatigue (-1.7 [95% CI -3.1, -0.4], $p = 0.01$) (Table). Improvements were generally maintained at 24 mos. Similar findings were seen in analyses using longitudinal mixed modeling. **Conclusions:** The BWEL WLI demonstrated QOL benefits for patients with breast cancer, resulting in significantly better physical function, global physical and mental health, and symptoms. Future analyses will evaluate which populations experienced the most benefit, as well as the relationships among QOL, symptoms, and weight loss. **Support:** U10CA180821, U10CA180882, UG1CA189823; U10CA180820; U10CA180868; U10CA180863, CCS 707213; U10CA180888; UG1CA189858; <https://acknowledgments.alliancefound.org>. **Clinical trial information:** NCT02750826. **Research Sponsor:** National Cancer Institute/U.S. National Institutes of Health; UG1CA189858; U10CA180821, U10CA180882, UG1CA189823; U10CA180820; U10CA180868; U10CA180863, CCS 707213; U10CA180888; U10CA180820; U10CA180868; U10CA180888; Susan G Komen Foundation; Breast Cancer Research Foundation; American Cancer Society.

Analysis of covariance-adjusted least squares means values at 6-mos adjusted for baseline scores.

QOL/Symptom Attributes	HE	WLI	Between arm difference (95% CI)*	P value
Physical Function	47.1	49.0	1.9 (0.8, 3.0)	<0.001
Global Physical Health	46.2	48.1	2.0 (0.9, 3.0)	<0.001
Global Mental Health	48.6	49.9	1.3 (0.2, 2.4)	0.03
Social Roles and Activities	52.7	55.0	2.3 (1.1, 3.6)	<0.001
Anxiety	50.2	50.0	-0.2 (-1.6, 1.2)	0.77
Depression	47.5	47.5	-0.0 (1.2, 1.2)	0.96
Fatigue	50.6	48.9	-1.7 (-3.1, -0.4)	0.01
Sleep Disturbance	51.0	51.1	0.1 (-0.6, 0.8)	0.80
Pain Interference	51.3	50.3	-1.0 (-2.4, 0.4)	0.15

*Positive differences in positive attributes and negative differences in negative attributes favor WLI arm.