



Alliance A011401: Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer

Jennifer Ligibel, MD

Dana-Farber Cancer Institute

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Rationale



Rationale

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Obesity is an established risk factor for poor outcomes in early-stage breast cancer. A meta-analysis of more than 200,000 women with Stage I-III breast cancer found that obese women had a 35% higher risk of breast cancer mortality and a 41% higher risk of all-cause mortality compared to normal weight women.

The **Breast Cancer Weight Loss (BWEL)** trial is a phase III randomized controlled trial that will evaluate the impact of a weight loss intervention on disease recurrence and other endpoints in overweight and obese women with stage II-III breast cancer.

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Primary

- To evaluate the impact of a telephone-based weight loss intervention (vs control) on invasive disease-free survival (iDFS) in overweight and obese women with stage II-III breast cancer.

Secondary

- To evaluate the impact of the weight loss intervention upon overall survival OS distant disease free survival (DDFS), co-morbidities and weight
- To evaluate the impact of the weight loss intervention upon iDFS and OS in subsets of participants based on menopausal status and tumor hormone receptor status



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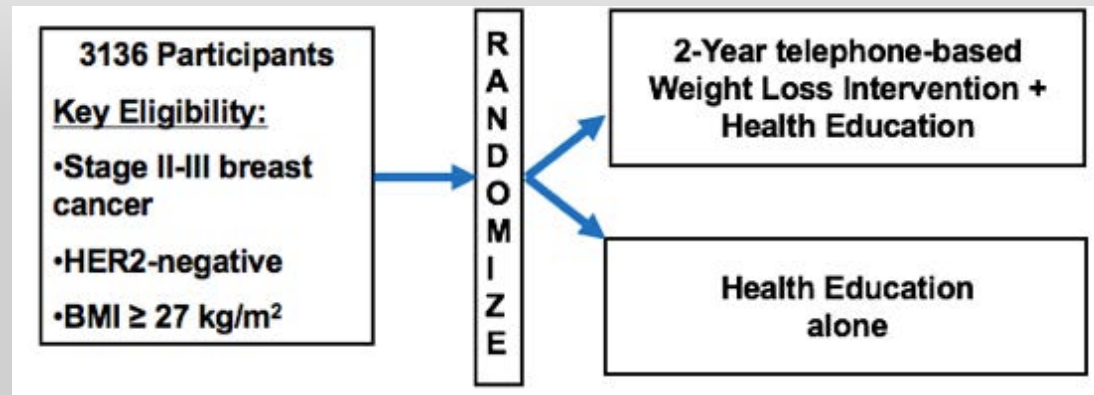
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Methods

- Participants randomized 1:1 to weight loss intervention + health education program or to health education alone (control)
- Stratification factors: menopausal status (pre/peri vs post) and race/ethnicity (African American, Hispanic, or Other)
- Sample size of 3,136 participants yields 85% power to detect a HR of 0.80; 4.1% decrease in iDFS events in intervention vs control





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- Breast cancer diagnosed within the last 12 months
- Her-2 negative
- ER and/or PR+: node positive and/or T3 tumor
- TNBC: any stage II or III breast cancer (excluding IBC)
- Body mass index ≥ 27 kg/m²
- Fluent in English or Spanish
- Completed chemotherapy, surgery and radiation (if administered)

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Weight Loss Intervention

- Telephone-based program, supplemented by print/web-based materials
- Based on Diabetes Prevention Program, Look AHEAD and LISA studies, with updates to nutritional recommendations
- Each participant is paired with a weight loss coach, based at centralized call center at the Dana-Farber Cancer Institute
- Intervention includes 42 planned calls over the 2-year intervention
- Target intervention goals include:
 - 10% weight loss (individual); average weight loss goal 7%
 - 500-1000 kcal/day caloric restriction
 - 150-225 minutes of weekly physical activity

Health Education Intervention

- Materials supporting healthy lifestyle (cookbook, water bottle, informational mailings)
- Webinars on focused breast cancer survivorship
- Study newsletter
- Subscription to health magazine



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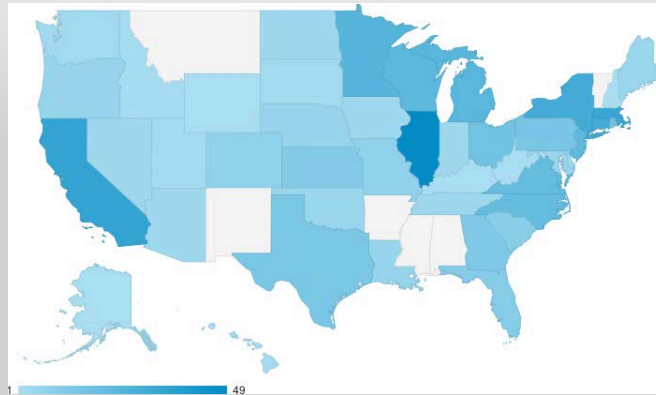
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Enrollment



- 1,994 participants randomized from **49** states and **5** provinces
- Canada
- United States
 - Midwest
 - Northeast
 - West
 - South

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Study Status

- Protocol activated in 8/2016 (9/2017 in Canada)
- Opened to Spanish-speaking participants 3/2018
- Protocol open to enrollment at 1984 US and 17 Canadian centers
- Completion of enrollment anticipated 7/2020
- Primary results anticipated late 2023



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