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
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Rationale

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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Objective

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) and 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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Rationale
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Study Schema
Methods
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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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**Key Eligibility Criteria**

- 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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Enrollment

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

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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Funding Support

Alliance A011401 is funded by the National Institutes of Health through National Cancer Institute grant awards, U10CA180821, U10CA180882, U10CA180820, U10CA180868, U10CA077202, and in part by Susan G. Komen Foundation, Breast Cancer Research Foundation, American Cancer Society; in kind: Fitbit Corp, Nestlé Health Science, Osiri Corp.

Clinicaltrials.gov identifier: NCT02750826

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