RANDOMIZED PHASE III TRIAL EVALUATING THE ROLE OF WEIGHT LOSS IN ADJUVANT TREATMENT OF OVERWEIGHT AND OBSESE WOMEN WITH EARLY BREAST CANCER

Key Eligibility Criteria (see Section 3.0 for a full list of eligibility criteria):
- Histologic diagnosis of invasive breast cancer within the past 12 months
- Her-2 negative
- Patients must have Stage II or III breast cancer. Eligible TNM stages include (see Section 3.2.1 for definitions):
  - ER and PR negative: T2-3N0 or T0-3N1-3 (patients with disease T0N0, T1N0 and T1N1mi disease are not eligible)
  - ER and/or PR positive: T0-3N1-3, or T3N0 (patients with T0N0, T1N0, T2N0 and T1-2N1mi disease are not eligible)
- All adjuvant or neoadjuvant chemotherapy, radiation and surgery completed at least 21 days prior to registration
- Participants must be women
- Age ≥ 18 years
- ECOG Performance Status 0 or 1
- No history of other malignancy within past 4 years and no comorbid conditions that would cause life expectancy of less than 5 years (see Section 3.2.6 for complete criteria)
- No diabetes mellitus currently being treated with insulin or sulfonylurea drugs
- BMI ≥ 27 kg/m² at the time of study enrollment
- Self-reported ability to walk at least 2 blocks (at any pace)
- Able to read and comprehend English or Spanish

Health Education Intervention (Arms 1 and 2):
All participants in both study arms will receive a 2-year health education intervention focused on breast cancer and general health topics. Patients will receive mailings of health education materials, materials supporting general health, nutrition, and physical activity such as a cookbook and a water bottle, newsletters a health magazine subscription, and invitations to webinars and teleconferences that focus on breast cancer and other health topics.

Weight Loss Intervention (Arm 2 Only):
The standardized, 2-year, telephone-based weight loss intervention will include individual weight loss, caloric restriction and physical activity goals for each participant. It will be administered through semi-structured phone calls delivered by trained coaches at the BWEL Call Center located at Dana-Farber Cancer Institute, and supplemented through print and on-line materials. The intervention will utilize a toolbox approach that will allow for tailoring for the individual participant.

Follow Up:
Patients are to be followed every 6 months for the first 3 years after study enrollment and then annually until 10 years from registration. The intervention will last 2 years or until disease recurrence/progression, new invasive primary cancer (other than BCC or SCC of skin that has been adequately treated) or patient withdrawal. Please refer to the full protocol text for a complete description of the eligibility criteria and intervention plan.