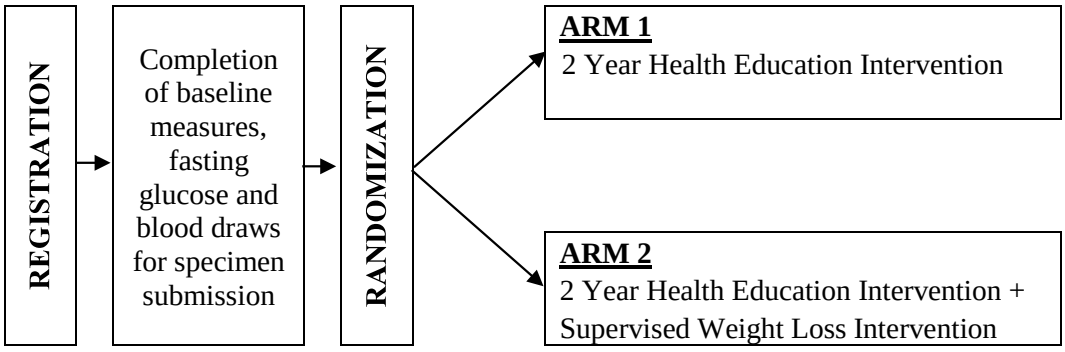
**RANDOMIZED PHASE III TRIAL EVALUATING THE ROLE OF WEIGHT LOSS IN ADJUVANT TREATMENT OF OVERWEIGHT AND OBESE WOMEN WITH EARLY BREAST CANCER**

**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
- Eligible TNM stages include (see Section 3.2.1 for definitions):
  - ER and PR negative: T2-3N0 or T0-3N1-3 (patients with T1N1mi disease are not eligible)
  - ER and/or PR positive: T0-3N1-3, or T3N0 (patients with 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/m$^2$ at the time of study enrollment
- Self-reported ability to walk at least 2 blocks (at any pace)
- Able to read and comprehend English

**Schema**




**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 brochures, 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.**