Protocol Title: Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer (BWEL Study)

Target Population: Overweight or Obese Women with Breast Cancer.

Summary: Primary objective of this trial is to compare the effect of a supervised weight loss intervention plus health education materials versus health education materials alone upon invasive disease free survival (IDFS) in overweight (BMI 27-29.9 kg/m2) and obese (BMI ≥ 30 kg/m2) women diagnosed with HER-2 negative, Stage II and III Breast Cancer. Patient follow up is up to a maximum of 10 years.

Key Inclusion Criteria:
- Subjects must have histologically confirmed invasive breast cancer.
- A core biopsy interpreted as invasive cancer meets this criterion.
- Neoadjuvant subjects should have no evidence of clinical T4 disease prior to chemotherapy and surgery
- Bilateral breast carcinoma is allowed provided diagnoses are synchronous.
- No evidence of metastatic disease.
- Eligible Tumor-Node-Metastasis (TNM) Stages include:
  - ER and PR Negative: T2 or T3 N0, T0-3N1-3.
    - Note: Patients with T1, N1mi disease are NOT eligible.
  - ER and/or PR Positive: T0-3N1-3 or T3N0.
    - Note: Patients with T1-2, N1mi disease are NOT eligible
  - Patients must have had a bilateral mammogram within 12 Months prior to registration.
- Prior Treatment:
  - All Triple Negative patients must receive chemotherapy of the treating physician's choice.
  - ER/PR+ patients must receive chemotherapy unless OncotypeDx or another genomic predictor score indicates that they are at low or intermediate risk of disease recurrence with endocrine therapy alone.
  - Concomitant biologic therapy, hormonal therapy, and bisphosphonates are acceptable.
- All subjects (both adjuvant and neoadjuvant) must have sentinel lymph node biopsy and/or axillary lymph node dissection. Sentinel lymph node biopsy alone is allowed in the following instances:
  - Sentinel lymph node biopsy is negative: pN0.
  - Sentinel lymph node biopsy is positive for isolated tumor cells only: pN0 (+).
  - Clinically node negative, T1-2 tumors with sentinel lymph node biopsy positive in < 2 lymph nodes without matted nodes and undergoing breast conserving surgery and tangential whole breast irradiation, or undergoing mastectomy and chest wall irradiation.
  - Patients who had a positive node prior to neoadjuvant chemotherapy, sentinel node alone is allowed if:
    - Sentinel node biopsy is negative after chemotherapy and either at least 2 sentinel nodes were removed or a clip was placed in the involved node prior to treatment.
    - ≤ 2 lymph nodes are positive for cancer and the patient is participating in A011202.
- All women who undergo breast conserving therapy must receive concomitant radiotherapy.
- Patients with hormone receptor positive breast cancer must receive at least 5 Years of adjuvant hormonal therapy in the form of tamoxifen or an aromatase inhibitor, alone or in combination with ovarian suppression.
- No diabetes mellitus currently treated with insulin or sulfonylureas.
- No prior bariatric surgery or planning to undergo this procedure within the next 2 Years after study registration.
- BMI ≥27 kg/m2 documented within 56 Days prior to study registration.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02750826

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