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

Alliance Group Meeting

November 4, 2016

Agenda

- Introduction to Study Team
- Overview of Alliance A011401 (BWEL) Study
  - Study rationale and objectives
  - Key eligibility criteria
  - Weight loss and health education interventions
  - Collection of study measures
- Update #01
- Patient Enrollment Process
- Specimen Submission Updates/Reminders/Tips
- Planned Update #2
- FAQs

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Study Team

- Jennifer Ligibel, MD, Study Chair
- Samantha Sublett, Protocol Coordinator
- Cristina Zabel, Data Manager
- Linda McCall, Secondary Statistician
- Tula Mahl, BWEL Call Center Project Manager

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Overview of Alliance A011401 (BWEL)

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Studies suggest that weight at diagnosis linked to prognosis in breast cancer

Meta-analysis of 82 studies looking at obesity and survival in breast cancer

	Breast Cancer-Specific HR [95% CI]	Overall HR [95% CI]
All patients	**1.35 [1.24-1.47]**	**1.41 [1.29-1.53]**
Premenopausal		1.75 [1.26-2.41]
Postmenopausal		1.34 [1.18-1.53]

Chan et al. Annals of Oncology 2014

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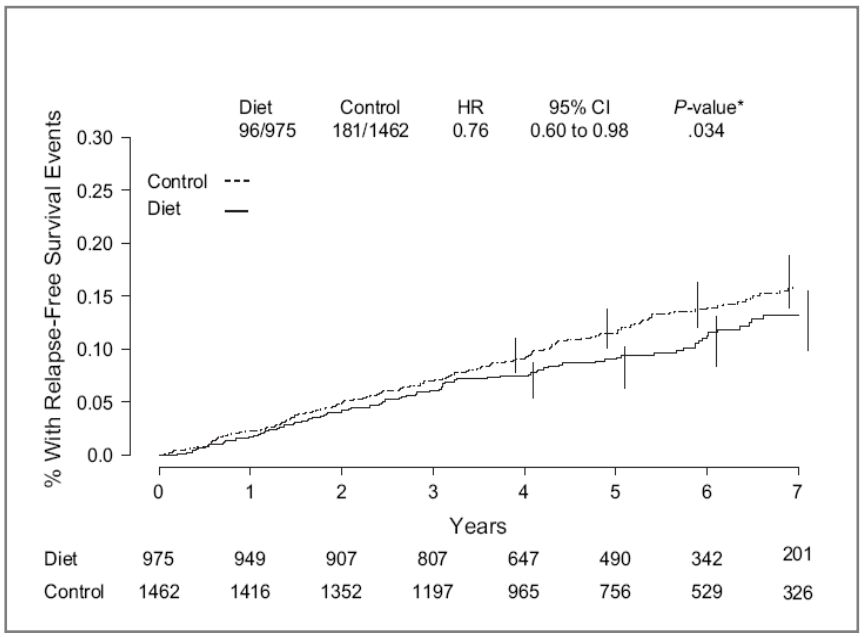
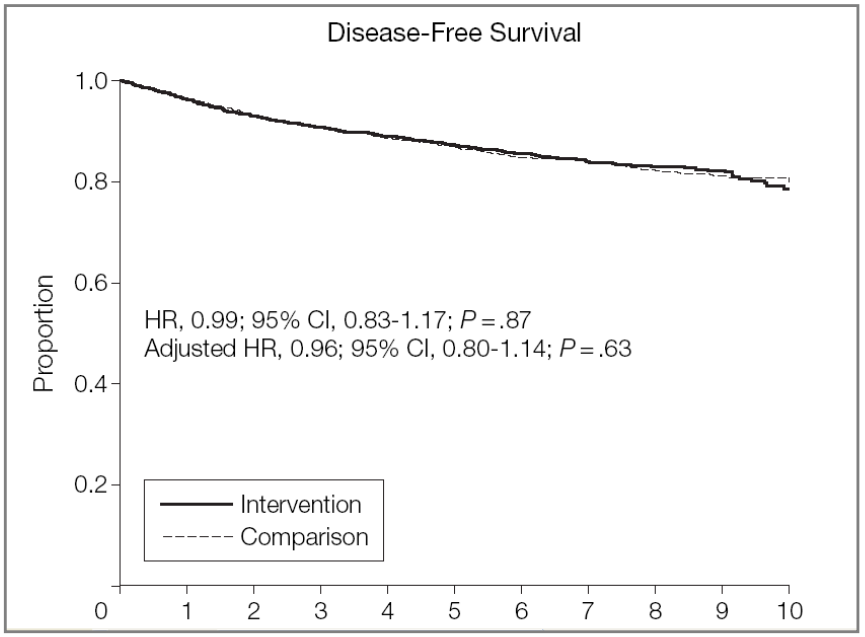
Indirect evidence that purposeful weight loss could lower risk of recurrence

WINS: Low fat diet



6 pound weight loss in diet group

WHEL: High fruit/veg, low fat



No weight loss in diet group

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Chlebowski et al, JNCI 2006: 98: 1767-76; Pierce et al., JAMA 2007; 298: 289-98..

What do WINS and WHEL tell us about lifestyle behaviors and cancer?

- WINS provides the only available evidence that a lifestyle intervention could affect cancer mortality
- Results of WINS and WHEL seem to provide evidence that weight loss, presumable achieved through restriction of energy intake, could impact cancer risk/outcomes
- Caveats:
  - Neither study was designed as a weight loss/energy restriction trial
  - We do not know if the women who did better in WINS were the ones who lost weight
  - Differences in study populations and intervention targets

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BWEL

The Breast Cancer Weight Loss Trial

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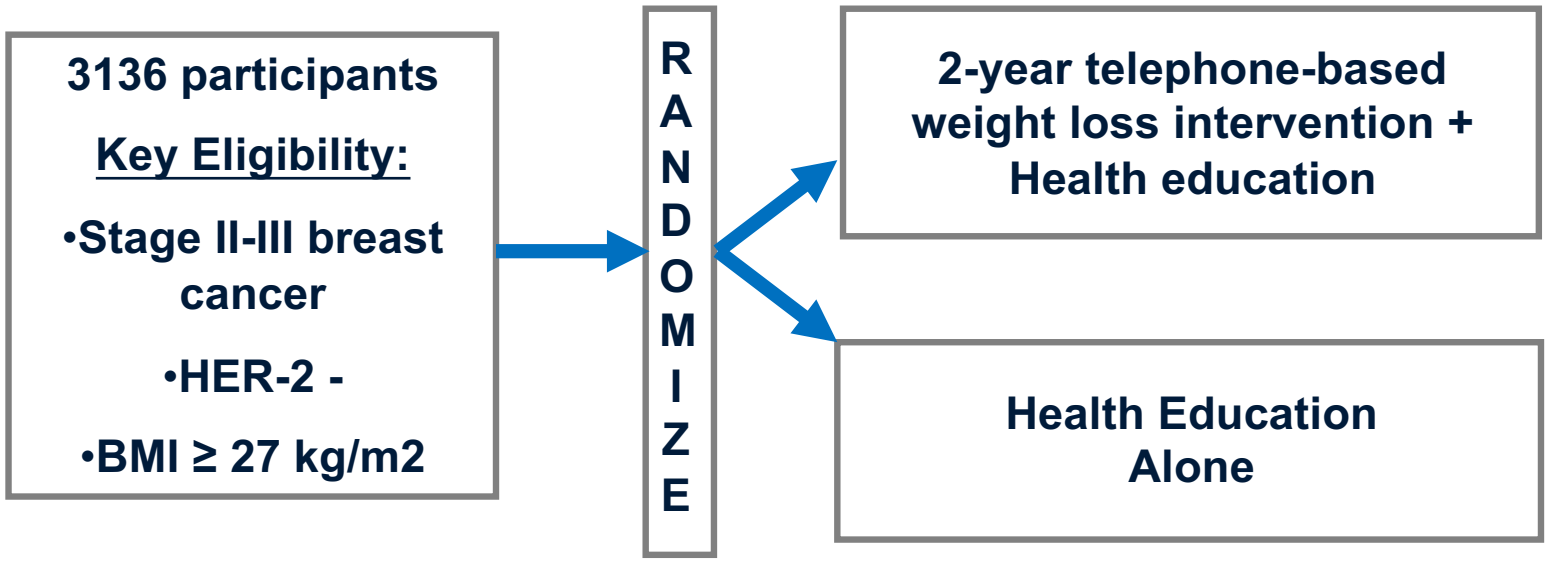
Study Schema



Conducted through NCTN/NCORP

Study activated: August 29, 2016

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Objectives

- **<u>Primary</u>:** **Assess the impact of a weight loss intervention upon Invasive Disease Free Survival (STEEP)**

- **Secondary:**
  - Assess the relationship between weight loss and IDFS and OS
  - Assess the impact of the weight loss intervention upon:
    - Overall mortality
    - Distant disease free survival
    - Weight change
    - Hospitalizations for cardiovascular disease or diabetes
  - To evaluate the impact of the weight loss intervention upon IDFS in subsets of participants defined by:
    - Hormone receptor status of the tumor
    - Menopausal status

- **Correlative end points**

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Select Eligibility Criteria

- Breast cancer diagnosed within past 12 months
- Her-2 negative
- Stage II-III
  - Triple negative tumors: T2-T3, N0-3; any T, N1-3
  - ER+: any T, N1-3
- Completed with all chemotherapy and surgery (current radiation and hormonal, bisphosphonate, and biologic therapies okay)
- Able to read and write in English (to open to Spanish-speakers in 2017)
- Life expectancy from other causes at least 5 years
- BMI ≥ 27 kg/m2
- Pre- or postmenopausal

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Exclusion Criteria

- History of prior invasive breast cancer within the past 5 years
- History of other malignancy within the last 4 years (except those with >95% likelihood of cure)
- Presence of metastatic breast cancer
- Participating in another study targeting similar pathways
- Pregnant, lactating or planning to become pregnant
- Diabetes requiring treatment with insulin or sulfonureas
- Self-reported inability to walk 2 blocks
- Serious digestive or absorptive problems
- Psychiatric disorders or conditions that would preclude participation

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Statistical Considerations

- **1:1 Randomization**
- **Stratification Factors:**
  - Menopausal status (pre or peri-menopausal s. post)
  - Hormone receptor status of the tumor (ER and/or PR + vs both -)
  - Race/ethnicity (African American vs. Hispanic vs. Other)
- **<u>Sample Size</u>: 3136 participants**
  - 85% power to detect HR 0.80
  - Equates to 4.1% absolute improvement in iDFS in intervention arm
  - Assumptions:
    - 4 years of accrual and 4 years additional follow up
    - Two-sided alpha 0.05
    - 5% loss to follow up and 10% complete discontinuation of intervention

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Weight Loss Intervention Overview

- Centralized, 2 year telephone-based intervention based on DPP, Look Ahead and LISA study

- Individualized goals:
  - 10% weight loss
  - 500-1000 kcal/day deficit
  - 700-900 kcal/week activity (150-200 minutes walking) in first 6 months, goal of 45-60 minutes of activity/day in maintenance phase

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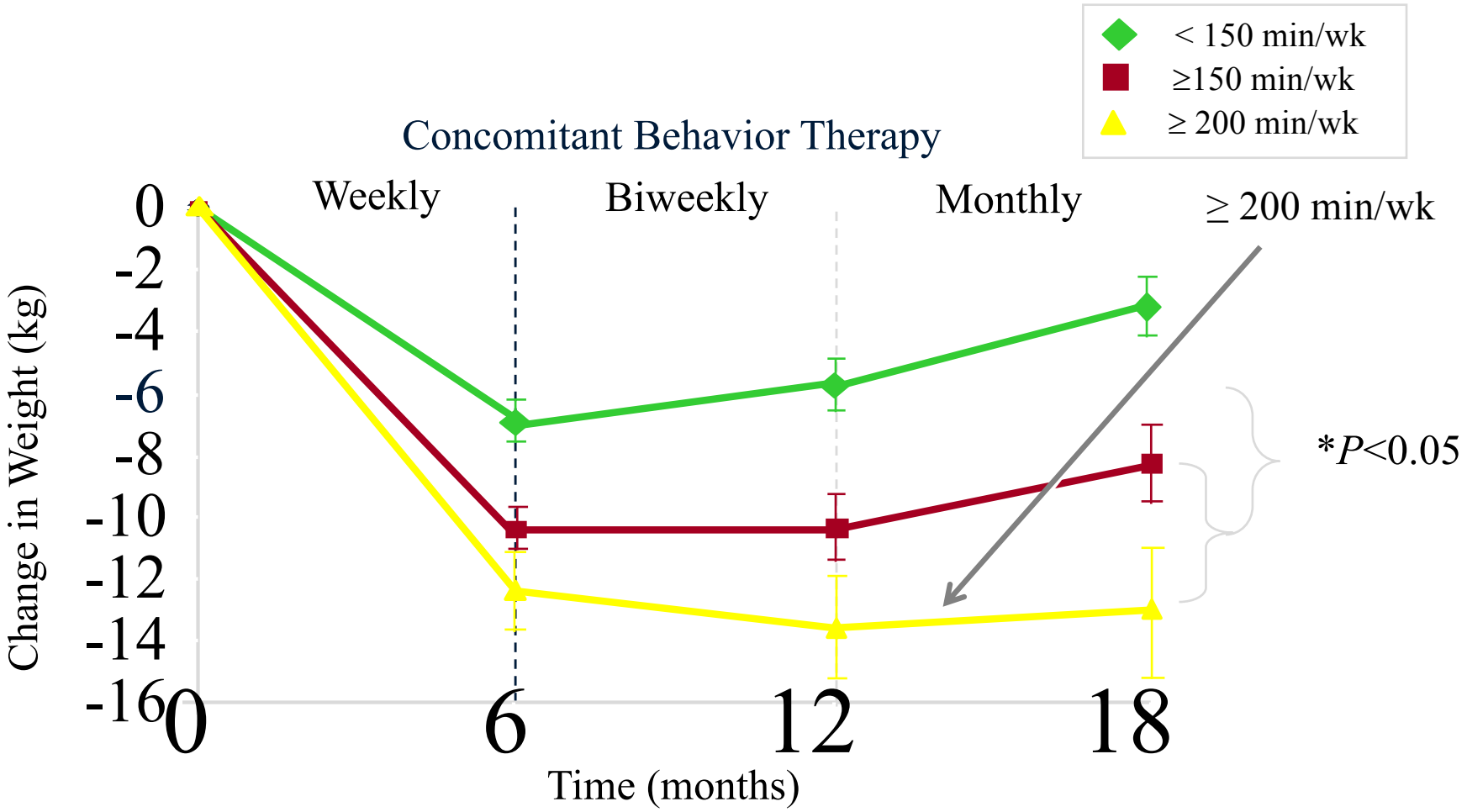
BWEL Dietary Principles

- The primary focus of the dietary component of the weight loss intervention will focus on caloric restriction
- The goal will be to achieve a 500-1000 kcal deficit per day
- Focus on portion control – patients lose 2-3 kg more with meal replacements than with calorie-reduced diets
  - **Supply commercial protein shakes**
  - Recipes for home-made shake and bar meal replacements
  - Structured menus

Basic diet includes 20-32% of calories from fat

High Levels of Physical Activity are Needed for Weight Loss Maintenance



Jakicic et al. JAMA 1999;282:1554.
Donnelly et al. Med Sci Sports Exerc 2009;41:459-71.

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Physical Activity

- Study will primary focus on aerobic activity; strength-training included in toolbox ™
- All participants provided with a Fitbit Charge HR
- Activity goals will be tailored based on baseline levels of physical activity
  - First 6 months: gradual increase to 150 minutes of moderate activity or 75 minutes of strenuous activity/week
  - Months 6-24: 45-60 minutes of moderate-intensity or 25-30 minutes of strenuous activity/day

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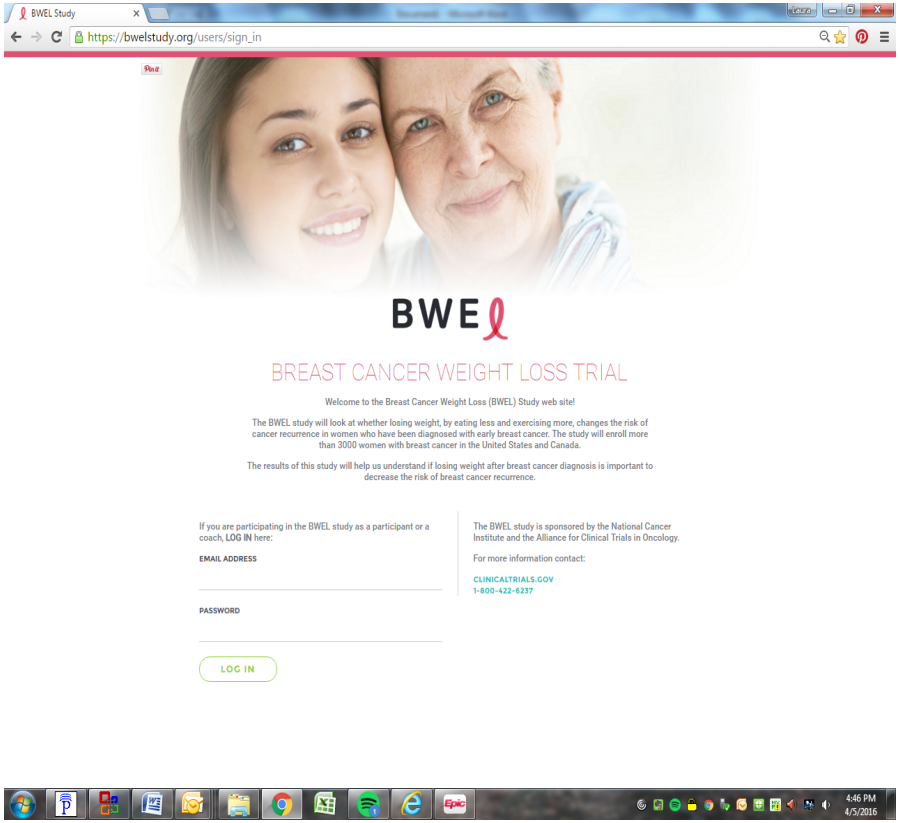
Intervention Implementation

- Intervention delivered by a behavioral coach located at Dana-Farber Call Center
- Patients receive 42 telephone calls over 2 years
  - Weekly calls weeks 1-12
  - Biweekly months 3-12
  - Monthly months 13-24
- Each call accompanied by print/web-based materials



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Health Educational Intervention

- Twice yearly mailings of materials regarding cancer survivorship and general health
- Twice yearly webinars regarding updates in breast cancer (following the San Antonio Breast Cancer Symposium and ASCO)
- Twice yearly study newsletter
- 2 year subscription to Health magazine


HARVARD MEDICAL SCHOOL

Harvard Women's Health Watch

VOLUME 22 • NUMBER 2 | OCTOBER 2014

How to lower your cholesterol without drugs

You can begin to reduce your "bad" LDL cholesterol by making a few simple changes in your diet.

"You don't have to follow an all-or-nothing approach. It's really a matter of common sense."

INSIDE

FIVE THINGS TO DO THIS MONTH

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Correlative Studies

- **Translational Science**
  - Fasting serum collected from all patients
  - Optional correlative substudy:
    - Collections of fasting whole blood
    - Collection of benign and malignant breast tissue from primary surgery

- **Health Behaviors-*First 514 participants***
  - Physical activity: accelerometer, 7-Day PAR
  - Diet: 24-hour dietary recall

- **Patient Reported Outcomes-*First 514 participants***
  - PROMIS 29
  - PROMIS fatigue scale
  - CARES
  - PROMIS sleep measure
  - BCPT Symptom Checklist
  - CIPN measure

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Study Measures

	Baseline	Month 6	Month 12 & 18	Month 24	Month 30 & 36	Annually
Tests & Observations						
History and physical	X	X	X	X	X	X
Anthropometric measures	X					
Medication & comorbidity questionnaire	X	X	X	X	X	X
Outcome assessment		X	X	X	X	X
Fasting blood draw	X	X		X		
Health behaviors and PRO (A011401-HO1): For the first 514 patients who enroll						
Health Behaviors	X	X		X	X*	
Patient Reported Outcomes	X	X		X	X*	
Tissue-based and genomic biomarkers A011401-ST1: For patients who consent						
Tissue sample (sent to Mayo PCO)	X					
Blood sample (sent to Mayo BAP)	X	X		X		

*Month 36 only

Assessment schedule: Baseline

Q6 months for 3 years

Annually to 10 years

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What measures will be collected at sites?

- Baseline:
  - Anthropometric measures:
    - Weight and height
    - Waist and hip circumference
  - Patient information
    - Disease and treatment information (from medical records)
    - Patient comorbidity and medication questionnaire
  - Correlatives:
    - Fasting blood collection (all patients)
    - Tumor block and fasting whole blood (optional)
  - PRO questionnaire-*first 514 patients only*

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Measuring height and weight

- Patients must have a BMI of at least 27 kg/m2 to be eligible for the study
  - Height and weight to establish eligibility must be collected within 56 days of study entry
  - Can be collected by clinical staff or obtained from the medical record

- An official baseline height and weight must be collected after registration and before the patient can be randomized
  - This height and weight must be done by study staff; clinic height & weight will not be accepted for the study.
  - Patient should be dressed in light indoor clothing and take off any hair ornaments, etc.
  - Patient should remove their shoes.

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Measuring waist & hip circumference

- These measures must be collected by study staff after registration but before randomization
- Measured twice in succession; record average in RAVE
- Use a non-elastic measurement tape measure and record all measurements in nearest 0.1 centimeters.
- The instruction that height, weight and circumference measures should be collected by staff blinded to prior measures will be removed with up-coming amendment

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Central measure collection

- Diet and physical activity measures
  - Collected:
    - From first 514 patients
    - At baseline, 6, 24 and 36 months
  - Measures:
    - Accelerometer
    - 7-Day Physical Activity Recall
    - 24-Hour Dietary Recall

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Support for sites

- Development of central IRB-approved recruitment materials
- SOP documents and training videos for collection of weight and waist/hip circumference measures
- Monthly study teleconferences starting after study activation (see Memorandum posted 6/15/16)
- Plan for in-person site PI meetings during annual ASCO/San Antonio meetings

What does the study involve?

Participants will be randomly assigned (like a flip of a coin) to one of two groups:

- **Weight Loss Group**

Participants will work with a weight loss coach and received telephone-based counseling.

Participants will receive 42 phone calls over two years from their weight loss coach on topics including:

- Calorie reduction
- Increasing physical activity
- Motivation and support

Participants will track foods they eat and exercise they do as part of the program. They will receive an activity tracker and scale to help track their progress.

OR

- **Health Education Group**

Participants will receive regular mailings on breast cancer topics and general health as well as invitations to attend online seminars that focus on breast cancer.

Who can participate in the study?

You may be eligible to participate if:

- ✓ You have been diagnosed with stage II or III breast cancer within the last 12 months
- ✓ You have completed surgery and chemotherapy (if given)
- ✓ You are interested in losing weight and have a body mass index (or BMI) greater than 27 kg/m^2
- ✓ You would like to receive information about health topics
- ✓ You are willing to be randomly assigned (like a flip of a coin) to one of two groups

What is required?

Participants will complete health questionnaires and take height and weight measurements and a fasting blood draw at different points throughout the study.

Who is conducting this study?

This study is being conducted by the Alliance for Clinical Trials in Oncology. The Alliance is part of a national research network funded by the National Cancer Institute (NCI).

For more information, contact:

[STAFF NAME]
[STAFF NUMBER]
[staff email address]

Or, you can ask your doctor about the BWEL Breast Cancer Weight Loss Study .

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Update #01

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Update #01

- Update #01 was circulated on 9/20/16 via Alliance Broadcast and subsequent CTSU Broadcast (on 9/22/16)
- See Alliance and CTSU websites for broadcast, as well as updated protocol and consent documents
- Until Update #01 is approved at your site, and until the new ICF is used, please follow your IRB of record guidelines re: notifying patients of new information contained in update
- Update includes minor clarifications as well as three major changes
- No changes were made to A011401-HO1 PRO booklets, so new booklets do NOT need to be ordered

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Update #01 Major Changes

- Eligibility:
  - Chest x-ray, 2 view (or Chest CT, or PET/CT), bone scans, and abdominal imaging are required ONLY IF clinically indicated or recommended by NCCN guidelines.
  - See changes in Section 3.2.1 as well as Section 5.0 and 8.2.

- Fasting Glucose performed locally:
  - Grey top tubes are not required and does not need to be performed immediately
  - Use institutional guidelines/standards (Accucheck is NOT acceptable)
  - See changes in Section 6.2 and 8.3

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Update #01 Major Changes

- Dietary and Physical Activity Recall Interviews
  - University of Arizona Cancer Center will be conducting a portion of the dietary and physical activity recall interviews for patients enrolled on the HO1 substudy (i.e. the first 514 pts enrolled on the study).
  - Changes have been made throughout the protocol document, and this information has been added to the informed consent document.

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Patient Enrollment Process

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Prior to registration

1. Identify patient and confirm eligibility

2. Obtain informed consent

3. Perform/confirm investigations listed in Section 5.0 “Prior to registration” column.
   - History and Physical, height and weight w/in 56 days
   - Mammogram w/in 1 year
   - Bone scan and/or chest/abdominal CT if clinically indicated (done at diagnosis)

4. Administer baseline patient questionnaire
   - Can be printed from Appendix I

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Registration

1. Register patient in OPEN via ctsu.org (see Section 4.5)

2. Within 48 hours of registration, fax the Patient Contact Information to Tula Mahl at 617-394-2632

3. For first 514 patients, remind patient that they will be getting a call from the BWEL Call Center at Dana-Farber to record their eating patterns and physical activity and will also receive a device in the mail that they will wear to track activity for 1 week

DO NOT randomize patients until baseline measures are collected!

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Prior to randomization

1. Measures collected at sites:
   - Collect fasting blood specimens and send to Mayo biorepository
   - **Measure fasting glucose at site and complete fasting verification form**
   - Measure weight, height, waist and hip circumference

2. For patients enrolled on A011401-ST1 (optional)
   - Send tissue samples to Mayo biorepositiry (can be after randomization)
   - Fasting whole blood to Mayo biorepository

-

3. For patients enrolled on A011401-H01 (Mandatory for first 514 patients)
   - Administer A011401-HO1 PRO Questionnaire Booklet

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Diet and Exercise Measures

- Be aware that before patients are randomized they must also complete diet and exercise measures collected through BWEL call center
  - Diet and activity telephone interview
  - Wear accelerometer
- The BWEL call center will email site to let you know:
  - When patient is scheduled for diet and exercise interview
  - When accelerometer was sent to patient
- You will need to collect accelerometer and journal from patient and send back to BWEL call center

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Randomization

4. Randomize patient in OPEN via ctsu.org (see Section 4.5)

5. Reference patient-completed baseline questionnaire for entering stratification factors. See Section 4.7.

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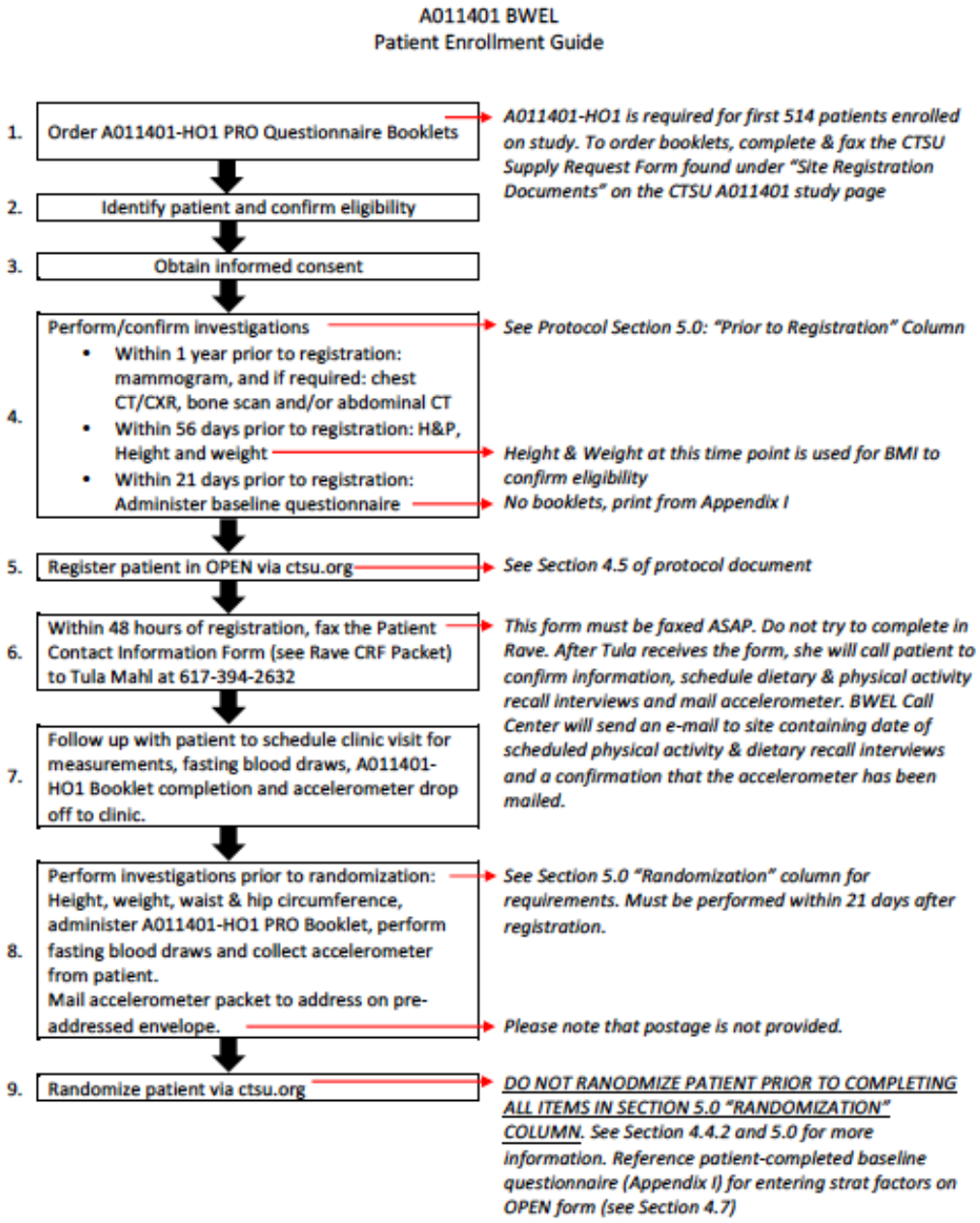
A patient enrollment guide was posted to the Alliance and CTSU websites on 10/1



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Specimen Submission Reminders & Tips

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Biorepository Contacts

- Non-paraffin embedded specimens (i.e. serum, plasma, blood)
  - Roxann Neumann: neumann.roxann@mayo.edu
  - See also under “Protocol Contacts” on Page 2 of protocol
- Paraffin embedded specimens
  - Amanda Sand: Sand.Amanda@mayo.edu
  - Helen Tollefson: Tollefson.Helen@mayo.edu
- If your question has regulatory, protocol or other implications, please cc protocol coordinator on your e-mail

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10/1 Memo: Specimen Submission

- The whole blood sample collection and submission instructions for A011401-ST1 need immediate modification in **Section 6.2.4 Blood sample submission (A011401-ST1).**

- This change was announced via memorandum on 10/1 and will be made in an upcoming amendment.

- Please follow the directions on the 10/1 memo for ST1 procurement and submission until an update is circulated.

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Tubes

- There are no kits for this study right now.
- With Update #02, we will change the protocol so that number of tubes is not dictated, only total volume (i.e. from “3 x 5 mL” to just “15 mL.” Use however many tubes at your site to obtain the required total volume for each sample type.
- Lithium Heparin Gel Separator tubes are acceptable.

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Collection & Storage

- Plastic EDTA purple top tubes may be frozen. Do not aliquot EDTA whole blood into 2 mL cryovials.
- Do NOT freeze glass tubes. If only glass EDTA tube available at site, pour EDTA whole blood into 5 mL Cryovials.
- Serum and Plasma samples should be aliquoted into 2 mL cryovials for a total of (4-6) 2 mL cryovials for each sample type.
- If you do not have a freezer that meets protocol requirements, then you must ship specimen on the same day as collection.

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Shipping

- Specimens can be shipped Monday – Friday. DO NOT SHIP SPECIMENS ON SATURDAY.
- Samples may be batch shipped provided site meets -80 temp requirements per protocol.
- There are two separate shipping addresses:
  - Serum, blood and other non-paraffin embedded specimens must be sent to the Mayo BAP at the address provided in Section 6.2.1 of protocol.
  - FFPE blocks for the ST1, must be sent to the Mayo PCO see address provided in Section 6.2.1 of protocol.

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Shipping cont.

- When shipping with couriers other than FedEx, be sure to ask for signature upon delivery.

- If possible, please e-mail Mayo on day of shipping with study ID, patient ID and tracking number.
  - For FFPE samples: e-mail Amanda Sand at Sand.Amanda@mayo.edu and Helen Tollefson at Tollefson.helen@mayo.edu
  - For blood, serum and plasma: e-mail Roxann Neumann at Neumann.roxann@mayo.edu

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Planned Update #2

- Make N1mi ineligible
- Mandate that patients with TNBC receive chemotherapy (of MD choice)
- Allow patients with T3 tumors and sentinel node dissections with ≤ 2 involved nodes to undergo RT in place of nodal dissection
- Clarify that patients who receive neoadjuvant chemotherapy can be eligible for study participation based on either clinical stage pre-treatment or yp stage post treatment

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Planned Update #2 cont

- Eliminate need for study staff to be blinded to prior anthropometric measures

- Simplify specimen collection:
  - Specify total volume of blood to be collected but not size of tube
  - Eliminate need for second centrifugation
  - Add language that specimens would ideally be processed with pre-specified time frame

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FAQs

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Questions: Best Practices

- For questions, try e-mail first. Include the following individuals on ALL e-mails (see protocol pg 1 for contact info):
  - Dr. Jennifer Ligibel (Study Chair)
  - Samantha Sublett (Protocol Coordinator)
  - Cristina Zabel (Data Manager)
  - Please also cc relevant personnel as needed: i.e. nursing contact, biorepository contact, statistician, etc.
- If you do not receive a response within 48 hours, follow-up via e-mail or call Samantha.
- DO NOT address questions to BWEL Call Center general e-mail or Tula Mahl (BWEL Call Center manager)

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Resources

- Study Memoranda:
  - CRP Webinar schedule (6/16/16)
  - ST1 Whole Blood Sample Specimen Collection & Submission Change (10/1/16)

- Supplemental Materials
  - List of eligible/ineligible diabetes medications
  - Monthly CRP Webinar Slides & Video for each webinar
  - Patient enrollment guide
  - BWEL Height and Weight Protocol
  - Site Educational Slides
  - Patient brochure & flyer

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FAQs: Eligibility

Is it required that patients receive chemotherapy in order to be considered eligible?

No, it is not a requirement that patients be treated with chemotherapy. However, if they were, they must have completed treatment at least 21 days prior to registration.

If a patient had another cancer within the last 4 years, how is the likelihood of cure defined?

We recognize that this is subjective. There was a desire to not exclude patients with thyroid cancers, early endometrial cancers, superficial melanomas, etc.. Discuss with the treating physician first, and then confirm with Dr. Ligibel if there is a question as to whether the patient is eligible or not

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FAQs: Eligibility

My patient was diagnosed outside of the 12 month window in the eligibility (or doesn't meet another criteria). Can we be granted a waiver or exception?

The Alliance and/or Study Chair cannot grant any eligibility waivers or exceptions. We are sorry, but if the patient clearly doesn't meet the criteria outlined in Section 3.2, they are ineligible.

Please note that this differs from windows outlined in other sections of the protocol (i.e. Section 5.0, 8.3, etc.). For example, if the patient is not randomized within 21 days of registration, they are still eligible to continue on to randomization. This is considered a departure from the protocol, but does not make the patient ineligible.

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FAQs: Eligibility

ER/PR

ER/PR negative is defined as <1% staining of both ER and PR. Otherwise patient is considered HR+

Margins

Margins must be negative for invasive cancer. If DCIS is present at the margin, re-excision is preferred, but a boost is an acceptable alternative for DCIS close to the margin.

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FAQs: Coenrollment

- Please keep in mind that patients are NOT eligible for BWEL until they have completed chemotherapy.

- Coenrollment allowed (from an A011401-perspective):
  - PALLAS, S1207 (during randomized everolimus)
  - NSABP 54I (PENELOPE)
  - NRG-BR003 (only after completing protocol therapy)
  - B-55 (and other PARP trials)

- Coenrollment not allowed: EA1131, or any study while patients are still receiving chemotherapy

- You MUST confirm with the other trial study chair that enrollment onto BWEL is acceptable from their perspective

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FAQs: Diabetes Medications

A list of eligible/ineligible diabetes medications was posted to the Alliance website on 11/1 and will be available on the CTSU shortly.

List of Eligible/Ineligible Diabetes Medications[1]

ELIGIBLE	INELIGIBLE
Biguanides • Metformin (Glucophage) • Metformin liquid (Riomet) • Metformin extended release (Glucophage XR, Fortamet, Glumetza) **Thiazolidinediones (TZDs)** • Pioglitazone (Actos) • Rosiglitazone (Avandia) **DPP-4 Inhibitors** • Sitagliptin (Januvia) • Saxagliptin (Onglyza) • Algoliptin (Nesina) • Linagliptin (Tradjenta) **GLP-1 receptor agonists** • Exenatide (Byetta) • Liraglutide (Victoza) • Albiglutide (Tanzeum) • Dulaglutide (Trulicity) **SGLT2 inhibitors** • Canagliflozin (Inovanka) • Dapagliflozin (Farxiga) • Empagliflozin (Jardiance) **Meglitinides** • Repaglinide (Prandin) **D-Phenylalanine Derivatives** • Nateglinide (Starlix) **Alpha-glucosidase Inhibitors** • Acarbose (Precose) • Miglitol (Glyset) **Bile Acid Sequestrants** • Colesevelam (Welchol) **Combination Pills** • Pioglitazone/Metformin (Actoplus Met) • Sitagliptin/Metformin (Janumet, Janumet XR) • Saxagliptin/Metformin (Kombiglyze) • Alogliptin/Metformin (Kazano) • Alogliptin/Pioglitazone (Oseni) • Empagliflozin/Linagliptin (Glyxambi) • Empagliflozin/Metformin (Synjardy) • Canagliflozin/Metformin (Invokamet) • Repaglinide/Metformin (Prandimet) • Dapagliflozin/Metformin XR (Xigduo XR) • Linagliptin/Metformin (Jentadueto) • Rosiglitazone/Metformin (Avandamet)	**Sulfonylureas** • Glimepiride (Amaryl) • Glyburide (Diabeta, Micronase) • Glipizide (Glucotrol, Glucotrol XL) • Micronized glyburide (Glynase) • Tolbutamide (Orinase) **Combination Pills** • Glyburide/Metformin (Glucovance) • Glipizide/Metformin (Metaglip) • Pioglitazone/Glimepiride (Duetact) • Rosliglitazone/Glimepiride (Avandryl) **Insulin** • Insulin glulisine (Apidra) • Insulin lispro (Humalog) • Insulin aspart (Novolog) • Insulin glargine (Lantus) • Insulin detemir (Levemir) • Insulin isophane (Humulin N, Novolin N)

[1] Information found on Mayo Clinic, UCSF, Joslin websites

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