



***Plenary Session: Integrative Innovations in Digital Health Technologies with Cancer Patients and Survivors***

# **The Breast Cancer Weight Loss (BWEL) Trial**

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*SIO Annual Meeting*  
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# Objectives

- Review the rationale for and design of the BWEL study
- Discuss the role of health technology in study implementation

# 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*

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

**Objective: Evaluate the effect of weight loss, achieved through a lifestyle intervention, on disease recurrence and survival in overweight and obese women with breast cancer**

# Considerations shaping trial design

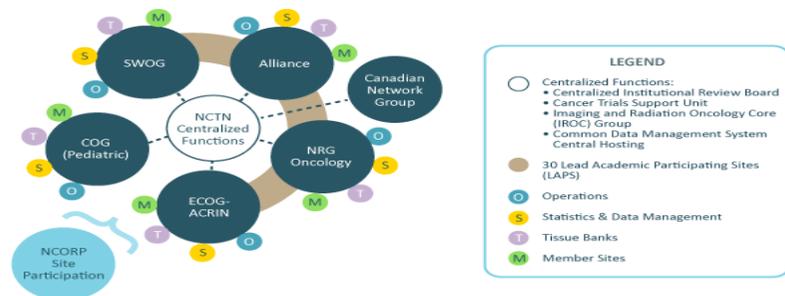
- **Breast cancer is a common disease**
  - Around 250,000 new cases expected in 2017
  - Approximately 40,700 deaths
- **Most cancers are early-stage at diagnosis**
  - 61% localized to the breast (stage I-IIa)
  - 34% have spread to lymph nodes (stage IIb-III)
  - 5% have spread distantly (stage IV)
- **Many women with breast cancer have excellent outcomes**
  - Stage I disease: 5 year relative survival ~98%
  - Stage II disease: 5-year relative survival ~93%
  - Stage III disease: 5-year relative survival ~72%

# Considerations shaping trial design cont

- **Breast cancer mortality, and obesity, not distributed evenly**
  - Prevalence of obesity in Black and Hispanic significantly higher than in Whites; mortality rates also greater
- **Weight loss has other health benefits for cancer survivors**
- **Participant population must:**
  - Be large enough to not “miss” a meaningful impact of weight loss on recurrence
  - Include a diverse population
  - Be small enough for the trial to be feasible

# NCI National Clinical Trials Network and NCI Community Oncology Program

- National network of institutions participating in cancer research
- NCTN: 4 adult and 1 pediatric oncology groups in US + 1 Canadian group
  - Each group supported by 2 infrastructure grants
  - Primarily academic sites
- NCORP: community based research program
  - Goal: To bring cancer clinical trials, as well as cancer care delivery research, to individuals in their own communities



# Opportunities and challenges in conducting research through the NCTN/NCORP system

- Opportunities

- System contains hundreds of geographically diverse clinics
  - Adequate pool of higher-risk patients
  - Geographic, racial, socioeconomic diversity
- Shared infrastructure for recruitment, data collection, protocol development, statistical support—COST EFFECTIVE

- Challenges

- System generally used for conduct of pharmacologic and local therapy interventions
  - Site study staff unfamiliar with collection of diet/exercise measures
  - No personnel at sites to conduct energy balance interventions

# Implications for Intervention Design

Interventions conducted through NCTN/NCORP system need to be centralized, delivered remotely

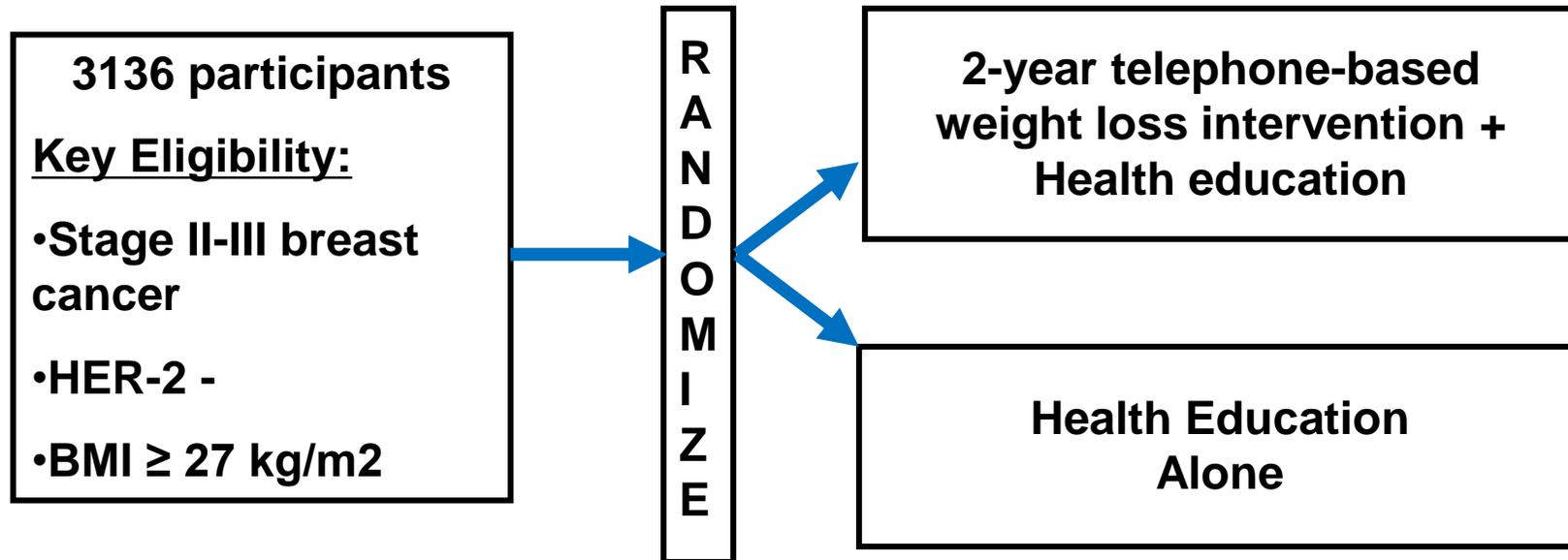
- Advantages:
  - » Easier standardization
  - » Cost effective
  - » Generalizable
- Primary disadvantage is difficulty in building relationship between participant and coach



**BWE** 

**The Breast Cancer Weight Loss Trial  
A011401**

# Study Schema



**Conducted through NCTN/NCORP**

*Powered to detect a 20% decrease in risk of recurrence in weight loss group  
(absolute difference in iDFS 4%)*

# Objectives

- **Primary:**     **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**

# 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, radiation, and surgery (current hormonal, bisphosphonate, and biologic therapies okay)**
- **Fluent in English, (Spanish opening summer 2017)**
- **BMI  $\geq$  27 kg/m<sup>2</sup>**
- **Pre- or postmenopausal**

# Weight Loss Intervention Overview

- **Centralized, 2 year telephone-based weight loss program**
  - Based on DPP, Look Ahead and LISA Study
  - Content updated to reflect recent research in weight loss in breast cancer
- **Each patient paired with a weight loss coach, based at DFCI**
- **Intervention goals:**
  - **10% weight loss**
  - **500-1000 kcal/day deficit**
    - » Portion control -- meal replacements, structured menus
    - » Basic diet stresses fruits, vegetables, whole grains, lower in fat
  - **Increased physical activity**
    - 150-200 minutes moderate-intensity activity in first 6 months
    - Goal of 45-60 minutes of activity/day in maintenance phase

# Intervention Implementation

- 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
- Toolbox used to help patients overcome specific barriers



The Breast Cancer Weight Loss Study



Lifestyle Participant Workbook  
Months 1-6

## The BWEL Lifestyle Balance Program Topics for the First 6 Months

The first 12 calls are scheduled once a week. The remaining calls in the program are once every two weeks.

Week	Topics
1	Welcome to the Lifestyle Program
2	Getting Started: Tipping the Calorie Balance
3	Not All Fats Are Created Equal: Eat Less of Most, More of Some
4	Cutting Calories by Controlling Your Portions
5	Move Those Muscles
6	Working With What's Around You: Cue Control
7	Problem Solving
8	Being Active: A Way of Life
9	Healthy Eating
10	Healthy Eating and Breast Cancer
11	Four Keys to Healthy Eating Out
12	Summary and Progress Review of the First Three Months
14	Talk Back to Negative Thoughts
16	The Slippery Slope of Lifestyle Change
18	Supermarket Smarts
20	Emotions and You
22	Handling Holidays, Vacations, and Special Events
24	Taking Stock and Celebrating Your Success

# BWEL Call Center and Coaching Team

- Hours of operation: 8am-11pm ET
- Staffed by 15 weight loss coaches
  - Dietitians
  - Exercise Physiologists
  - Nurses
  - Social workers
- Oversight
  - Call center manager
  - Behavioral Director
  - PI and Oversight Team
- Weekly training/oversight meetings



# Intervention Tools



- Patients randomized to weight loss intervention receive a number of tools to assist in achieving weight loss goals:
  - Lifestyle workbook
  - Wireless scale
  - Cookbook
  - Food scale
  - Protein meal replacement shakes (starting at week 5)
    - Supplied with up to 2 shakes/day months 2-6, 1 shake/day months 6-24
  - Activity tracker (week 16) with FitStar™ subscription
- Additional materials available as part of toolbox support
  - Examples: exercise DVD's, coupons for shoes or exercise classes, alternative dietary plans and cookbooks, etc

# BWEL Web Application

- Contains participant, coach and administrative portals
- Goals
  - Enhance participant engagement
  - Allow tracking of weight, exercise, diet
  - Facilitate communication
  - Implement intervention
  - Facilitate quality assurance



**BWEL**

BREAST CANCER WEIGHT LOSS TRIAL

Welcome to the Breast Cancer Weight Loss (BWEL) Study web site!

The BWEL study is looking at whether losing weight, by eating less and exercising more, changes the risk of cancer recurrence in women who have been diagnosed with early breast cancer. The study is enrolling more than 3000 women with breast cancer in the United States and Canada.

The results of this study are helping us understand if losing weight after breast cancer diagnosis is important to decrease the risk of breast cancer recurrence.

# BWEL Patient Portal

- **Enhance engagement with weight loss program**
  - Log food, exercise and weight
  - Provide visual depiction of study progress
- **Review study didactic materials**
- **Communicate with coaches**



# BWEL Coach Portal

- **Monitoring participants**
  - Viewing weight, exercise and diet data
  - Communicating with participants via email
- **Conducting coaching sessions**
  - Place and record calls
  - Taking notes
  - Assigning & reviewing worksheets
- **Call planning**
  - View schedule
  - Setup new appointments
  - Re-schedule appointments

The screenshot displays the BWEL Coach Portal interface for a participant named Jill BWEL. The header shows the date (OCTOBER 13, 2017), the participant's name (JILL BWEL), and study details (STUDY ID: Z-9, LAST LOGIN TIME: 10/13/2017 3:20 AM). A pink 'Call' button is visible in the top right corner. Below the header, there are navigation tabs for COALS, PROGRESS TRACKER, MESSAGES, NOTES, WORKSHEETS, and PROFILE. The 'Notes' section contains a warning message: 'This participant is at risk of dropping out of the study.' and a text input field with the placeholder 'Enter notes here...'. A 'VIEW CALL SCHEDULE' button is located to the right of the notes section. Below the notes, there is a table of notes with columns for COACH and NOTE. The table contains three entries, each with a coach name (Z-James Z-Gehan) and a note (Jill - only ate one donut today - getting better.) and a date (04/05/2017). A fourth entry has a longer note: 'Z-James Z-Gehan Here is a test note from today - March 20th Blah blah' with a date of 03/20/2017. A pink 'Email' button is positioned to the right of the notes table. At the bottom, there is a 'Calls' section with a table of call recordings. The table has columns for 'PLACED ON' and 'REC'. It shows three recordings: '23 MAY 2017 1:30 PM' (0m 6sec), '23 MAY 2017 1:23 PM' (0m 8sec), and '23 MAY 2017 11:14 AM' (0m 10sec). A pink 'Record' button is located to the right of the calls table. Navigation buttons for 'PREVIOUS', '1', '2', '3', and 'NEXT' are visible above the calls table.

# Health Educational Intervention

- Twice yearly mailings of materials regarding cancer survivorship and general health
- Twice yearly webinars regarding breast cancer survivorship
- Quarterly study newsletter
- 2 year subscription to Health magazine

**BWE**   
450 Brookline Ave, 5WS60  
Boston, MA 02215



**Fun Ways to Stay Active in the Fall**

Fall is here—kids are heading back to school and schedules are filling up fast. Here are some tips to help you stay active through this busy season:

- ◆ Go apple picking or for a walk in a corn maze. Nothing beats crisp fall air!
- ◆ Take a walk, hike, or bike ride to enjoy the fall foliage— wear layers.
- ◆ Plan “activity dates” with family or friends instead of meeting up for food or drinks. Teaming up with others helps keep motivation high.
- ◆ Sign-up for a walk or 5K—preparing for the event will help keep you active.
- ◆ Volunteer! It’s a great way to stay active while helping others.
- ◆ Take a dance, Zumba, or yoga class. They’re a fun way to get moving.
- ◆ Make TV time active. While watching, do sit-ups, squats, or other body weight exercises. Use a treadmill or stationary bike, if you have one at home.
- ◆ Go swimming— local YMCAs, fitness centers, and schools have indoor pools.



# Study Status

- **Trial activated August 29, 2016**
- **First patient enrolled August 30, 2016**
- **Current participating sites:**
  - >1055 US sites
  - 20 Canadian site
- **Enrollment: 823 patients randomized**
  - 46 states
  - 1<sup>st</sup> Canadian participant enrolled 11.10.2017!



# BWEL is a collaborative effort

- Wide-spread outpouring of enthusiasm on the part of patients and sites, especially amongst community practices
  - Target monthly rate of enrollment reached by 3<sup>rd</sup> month after activation
- Support from diverse group of public and private organizations
  - Government funders: CTEP, DCP, DCCPS through Alliance
  - Foundations: Susan G. Komen, Breast Cancer Research Foundation, American Cancer Society
  - Corporations- Fitbit, Nestlé Health Sciences, Harvard University Press, Osiri Corp



# Study team

- **PI: Jennifer Ligibel**
- **Co-Chairs**
  - **Correlative Science Co-Chair: Pam Goodwin (Co-PI)**
  - **Health Behaviors Co-Chair: Dawn Hershman (SWOG)**
  - **Community Oncology Co-Chair: Judy Hopkins**
  - **Health Disparities Co-Chair: Electra Paskett**
  - **Breast Committee Chairs: Eric Winer & Cliff Hudis**
- **Statistics:** Bill Barry, Linda McCourt, Amylou Dueck
- **Advocates:** Patty Spears and Liz Frank
- **Funding:** CTEP, DCP, DCCPS, ACS, Komen
- **Intervention Oversight Committee:**
  - **Chair: Tom Wadden**
  - **Behavioral Science: Catherine Alfano**
  - **Exercise Physiology: Melinda Irwin**
  - **Nutrition: Marian Neuhouser**
  - **Call Center: Linda Delahanty**
  - **Remote Intervention Delivery: Cyndi Thomson**
- **Steering Committee Members**
  - **Vered Stearn (ECOG)**
  - **Julia White (NRG)**
  - **Rachel Ballard (NIH)**
  - **Worta McCaskill-Stevens (NCI)**
  - **Linda Nebeling (NCI)**
  - **Vanessa Bernstein**