



Lessons from the BWE study – a weight management programme for breast cancer survivors

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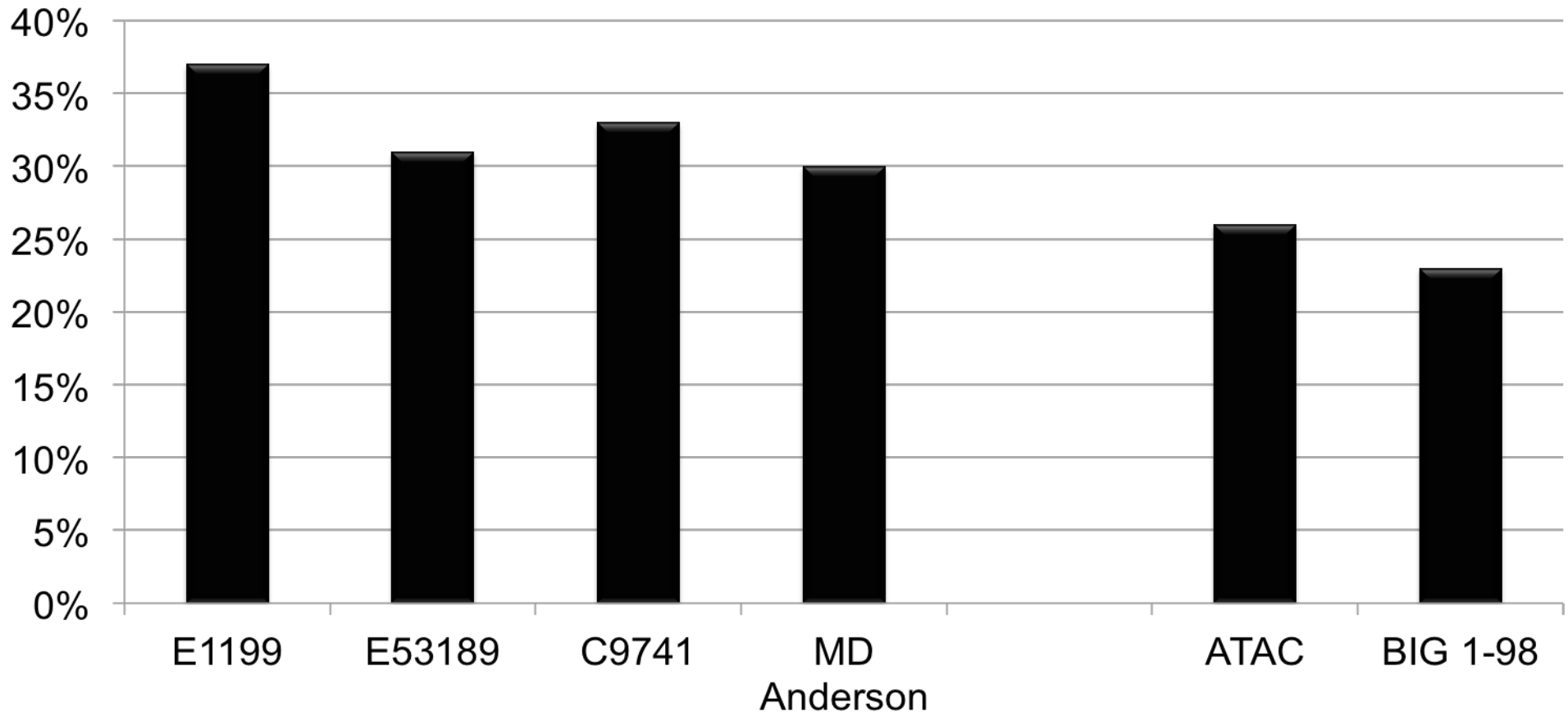
Obesity is associated with increased risk of mortality in women with breast cancer

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]

...yet obesity is common in breast cancer patients

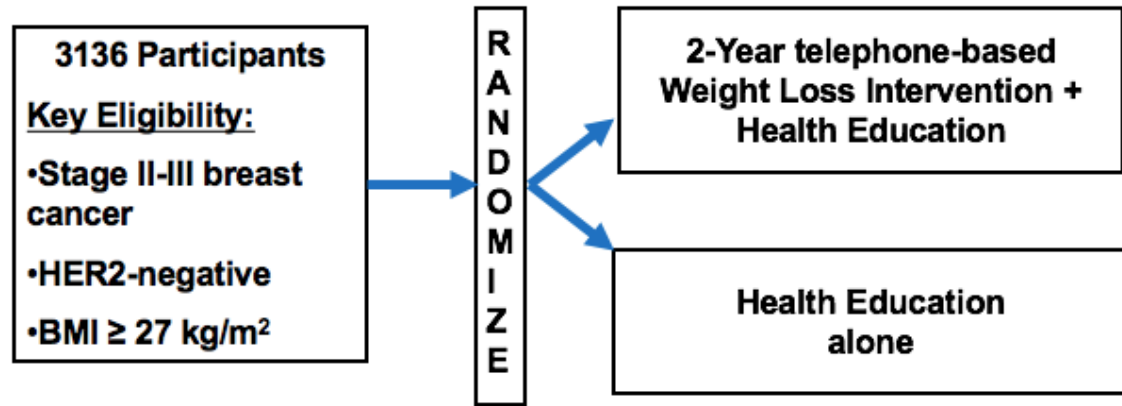
Prevalence of obesity at diagnosis in women with early breast cancer



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



The Breast Cancer Weight Loss Trial



Conducted through the North American NCTN and NCORP network of academic and community oncology clinics

Objectives and Statistical Considerations

- **Primary Objective:** Assess the impact of a weight loss intervention upon Invasive Disease Free Survival
- **Secondary:**
 - Assess the relationship between weight loss and recurrence and survival
 - Assess the impact of the weight loss intervention upon OS, breast cancer mortality and CVD
 - Determine impact of weight loss intervention on cancer outcomes based on:
 - Hormone receptor status of the tumor
 - Menopausal status
 - Correlative endpoints (HRQOL, tissue and blood biomarkers, etc)
- **Statistical Considerations**
 - Study has 85% power (one-sided $\alpha=0.025$) to detect HR 0.80
 - Equates to a 4.1% absolute reduction in recurrence in weight loss arm

How do you get patients to lose weight?

How do you administer a weight loss intervention through >1000 centers whose research experience has primarily focused on pharmacologic agents?

Develop standardized, centrally-delivered intervention

- **Standard program: 2 year telephone-based weight loss program**
 - Based on Diabetes Prevention Program, Look Ahead and LISA Studies
 - Content updated to reflect recent research in weight loss in breast cancer
- **Centralized delivery: each patient paired with a weight loss coach, based at DFCI**
- **Standard intervention goals:**
 - **10% weight loss**
 - **500-1000 kcal/day deficit**
 - **Increased physical activity**
 - 150-225 minutes moderate-intensity activity/week

Intervention Materials and Delivery

- 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
- Dana-Farber call center:
 - 15 coaches
 - Hours of operation: 8am-11pm ET



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

Find ways to individualize the intervention



- Patients randomized to weight loss intervention receive a number of tools to assist in achieving weight loss goals:
 - Wireless scale
 - Cookbook
 - Food scale
 - Protein meal replacement shakes
 - Activity tracker (Fitbit Charge3) 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

Use technology to build connections between participants and coaches



BWEL 

BREAST CANCER WEIGHT LOSS TRIAL

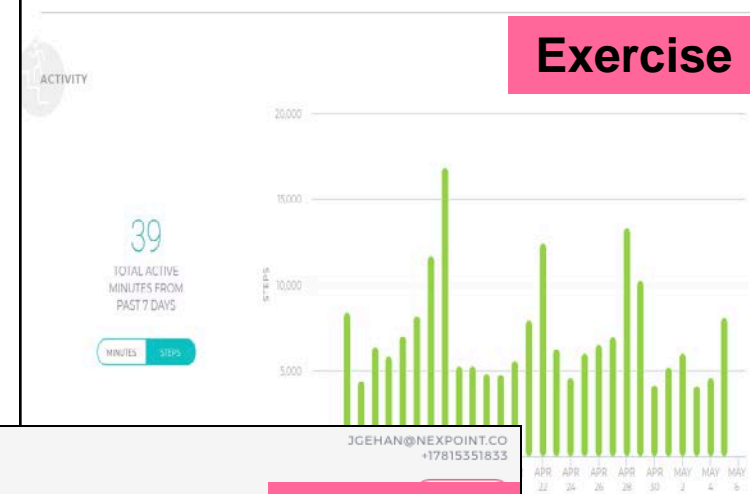
Welcome to the Breast Cancer Weight Loss (BWEL) Study web site!

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 will help us understand if losing weight after breast cancer diagnosis is important to decrease the risk of breast cancer recurrence.

BWEL Web Application

- Enhance engagement with weight loss program
 - Import data from activity monitor, scale, health tracking aps
 - Self/coach monitoring
- Facilitate communication
 - Place calls
 - Provide secure email portal
 - Display call schedule
- Measure quality of intervention



OCTOBER 13, 2017
JILL BWEL
STUDY ID: Z-9
LAST LOGIN TIME: 10/13/2017 3:20 AM

JGEHAN@NEXPOINT.CO
+17815351833

GOALS PROGRESS TRACKER MESSAGES NOTES WORKS

Call

Notes

This participant is at risk of dropping out of the study.

Enter notes here...

VIEW CALL SCHEDULE

SAVE NOTES

Notes

COACH	NOTE	
Z-James Z-Gehan	Jill - only ate one donut today - getting better.	04/05/2017
Z-James Z-Gehan	Jill - only ate one donut today - getting better.	04/05/2017
Z-James Z-Gehan	Jill - only ate one donut today - getting better.	04/05/2017
Z-James Z-Gehan	Z-James Z-Gehan Here is a test note from today - March 20th Blah blah blah Blah blah blah Blah blah blah Blah blah blah Blah blah blah Blah blah blah Blah blah blah Blah blah blah Blah blah blah	03/20/2017

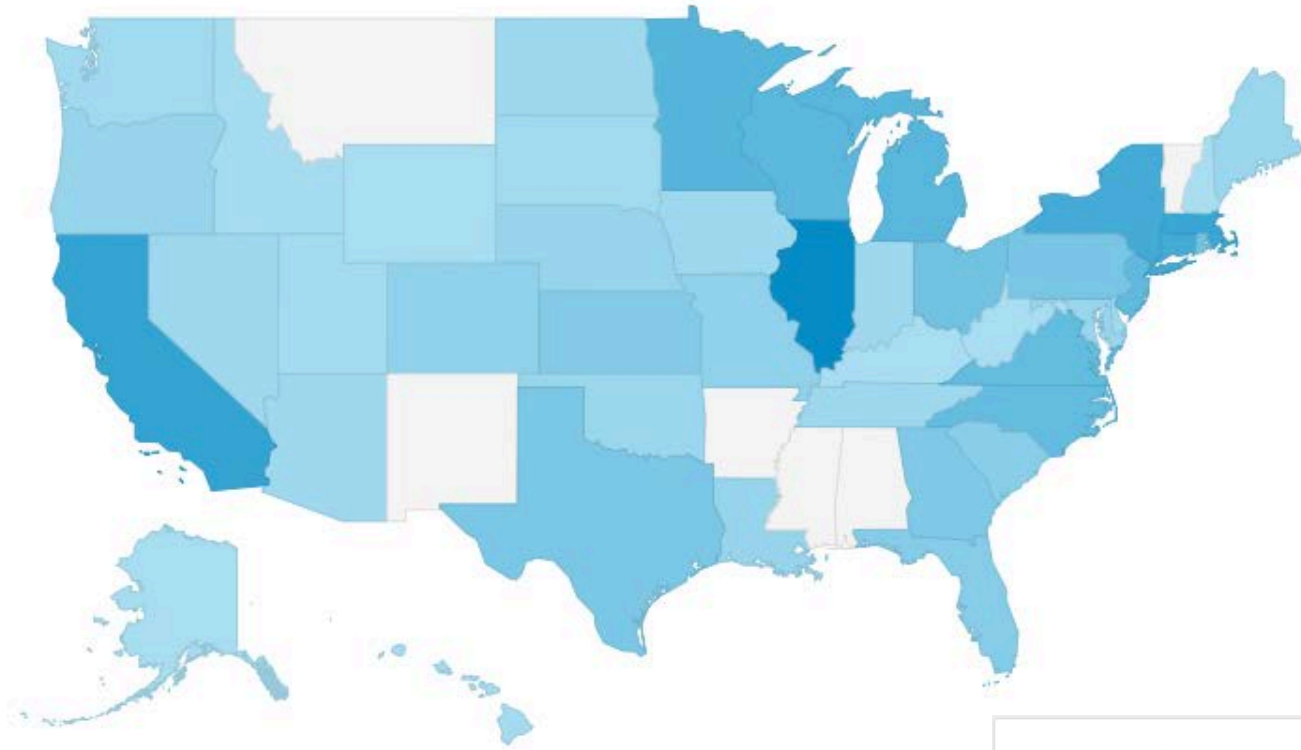
PREVIOUS 1 2 3 NEXT

Calls

PLACED ON	REC	
25 MAY 2017 1:50 PM	00:00	0m 6sec
25 MAY 2017 1:25 PM	00:00	0m 8sec
25 MAY 2017 11:14 AM	00:00	0m 10sec

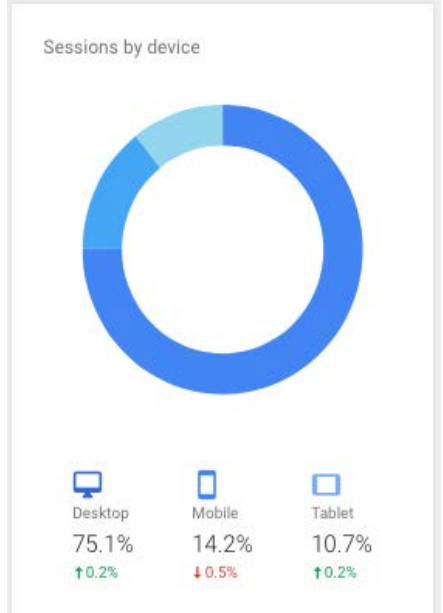
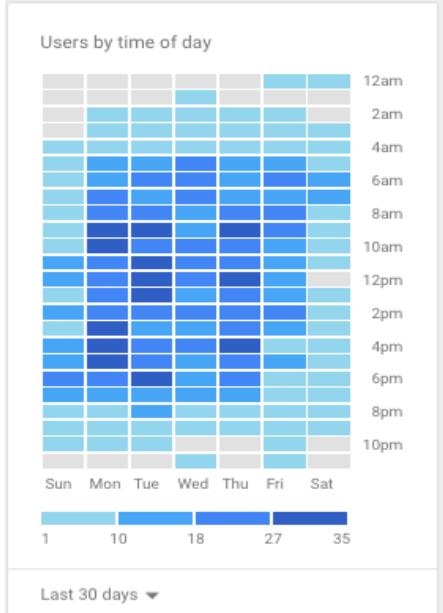
Record





BWEL app administrative capabilities

BWEL Web Application Users



Other opportunities: Correlative Science

- BWEL offers opportunity to explore biologic mechanisms underlying relationship between obesity and cancer risk/outcomes
- Longitudinal collection of biologic samples, connected to clinical outcomes
- Samples collected:
 - Fasting blood at baseline, 6 and 24 months
 - Malignant and benign breast tissue from primary surgery
- Goals:
 - Identify predictors of intervention benefit
 - Potentially define population to whom intervention should be prescribed
 - Develop intermediate biomarkers

How are we doing?

- **Trial activated August 29, 2016**
- **Current participating sites:**
 - >1127 US sites
 - 20 Canadian sites
- **Enrollment: 2026 patients randomized**
 - 49 states
 - 1st Canadian participant enrolled November, 2017
 - Study opened to Spanish-speaking participants March, 2018
- **Results expected 2024**



BWEL is not the only RCT testing impact of weight loss on breast cancer recurrence

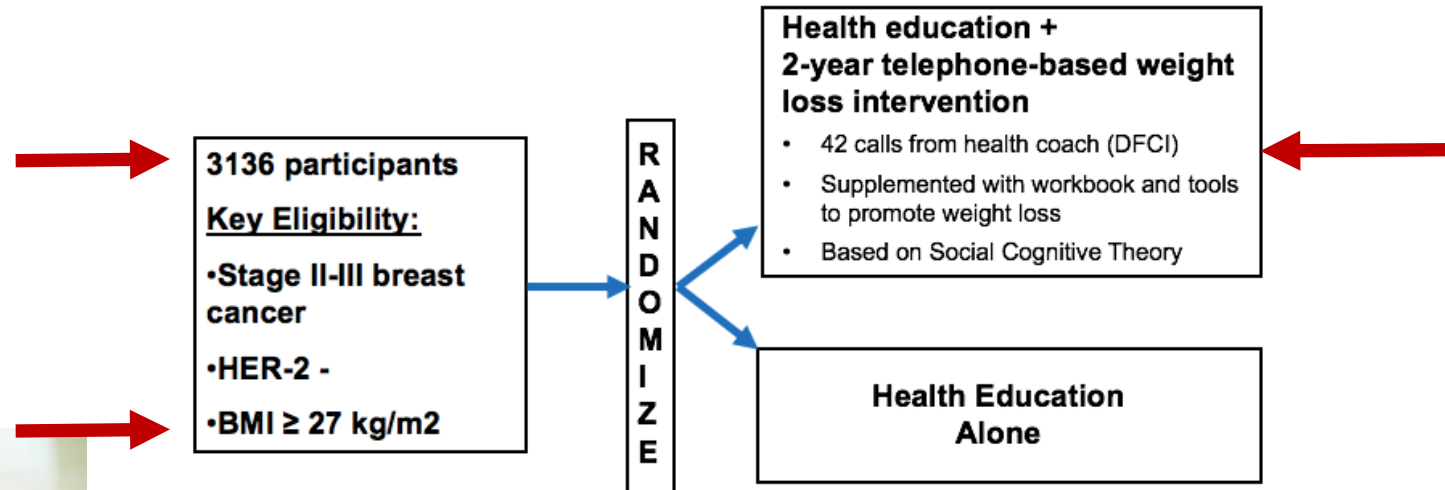
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N	3136	1241	2292
Location	US + Canada	Italy	Germany
Eligibility			
• Stage	II-III	I-III	II-III
• BMI	≥ 27 kg/m ²	None	24-40 kg/m ²
• Other		↑ testosterone/insulin Metabolic syndrome OR ER - cancer	
Intervention	2-yr Weight loss	4+ yr Med diet + Ex	2-yr Weight loss
1° End point	IDFS	IDFS	DFS



The Breast Cancer Weight Loss Trial



NCT02750826



- Interim weight change analysis; stopping rule applied if difference in weight change in intervention vs control group not $>4\%$ baseline body weight
- Passed interim analysis in March 2019

Weight loss interventions in breast cancer: Lessons learned

- Patient interest in weight loss interventions after breast cancer diagnosis is high
- Significant weight loss is feasible in breast cancer survivors
- Lifestyle intervention research is challenging in breast cancer survivors (as in other populations), with outcomes potentially limited by attrition and poor intervention adherence
- Large-scale trials provide important opportunity to study mechanisms through which weight loss/related factors could impact breast cancer risk and outcomes

BWE team and support

- **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: Ann Partridge and Lisa Carey (Eric Winer)**
- **Statistics:** Karla Ballman, Linda McCourt, Amylou Dueck
- **Advocates:** Patty Spears and Liz Frank
- **Funding:** CTEP, DCP, DCCPS, ACS, Komen, BCRF
- **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**