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Phase II Feasibility Study of a Weight Loss Intervention in Female Breast and Colorectal Cancer Survivors (SWOG S1008)

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Abstract

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OBJECTIVE—To test the feasibility of a 12-month weight loss intervention using telephone-based counseling plus community-situated physical activity (PA) in female breast (BC) and colorectal (CRC) cancer survivors.

METHODS—This multisite cooperative group study enrolled sedentary female, postmenopausal BC and CRC survivors with BMI ≥ 25 kg/m² to receive 12-month fitness center memberships and telephone counseling encouraging 150 minutes/week of PA and 500 kcal/day decrease in energy intake. Feasibility criteria included accrual, adherence and retention. Target weight loss was $\geq 5\%$.

RESULTS—Among 25 BC survivors, median baseline BMI was 37.2 (range 27.7-54.6), accrual occurred in 10 months, 60% and 28% met diet and exercise goals, 80% provided 12 month measures, and average weight loss was 7.6% (95%CI: -3.9% , 19.2%). Among 23 CRC survivors, median BMI was 31.8 (range 26.4-48.7), accrual occurred in 24 months, 61% and 17% met diet and exercise goals, 87% provided measures and average weight loss was 2.5% (95%CI: -8.2% , 13.3%).

CONCLUSION—It is feasible to recruit and retain BC survivors in a cooperative group diet and PA weight loss trial. BC survivors achieved clinically meaningful weight loss but did not meet *a priori* adherence goals. In CRC survivors, recruitment was more difficult and the intervention less effective.

Keywords

weight loss intervention; physical activity; dietary change; breast cancer; colorectal cancer

INTRODUCTION

A growing body of observational data suggests that higher BMI at diagnosis and following treatment is associated with poorer prognosis for breast cancer and possibly for colorectal cancer.¹⁻⁵ However, there are limited data on the effects of post-diagnosis weight loss.⁶⁻¹⁰ It is problematic to use observational data to examine the effects of post-diagnosis changes in weight on cancer outcomes as few people effectively achieve and maintain weight loss following a cancer diagnosis, and it is difficult to distinguish between unintentional and intentional weight loss. Therefore, trials are needed to formally test the hypothesis that weight loss following diagnosis improves clinical endpoints in both breast and colorectal cancer patient populations; some of these trials are ongoing.³

In addition, studies are needed not only to test the efficacy of behavior change interventions on cancer outcomes, but also on the effectiveness of an intervention to change the targeted behaviors, such as changes in diet and physical activity. If specific behaviors are identified as contributing to improved cancer outcomes, interventions that are effective in community settings need to be identified and then promoted and facilitated within clinical oncology settings. Moreover, it is important to identify behavioral interventions that are effective in specific cancer patient populations as it cannot be assumed that a “one-size fits all” approach will have the same uptake in all patient populations. To date, there have been few head to head comparisons on the effect of behavioral interventions in different cancer patient populations.^{11,12}

We conducted SWOG S1008, a single arm Phase II pilot and feasibility study of a weight loss intervention among sedentary female breast and colorectal cancer survivors with BMI $\geq 25 \text{ kg/m}^2$. The primary aims of the study were 1) to determine the feasibility of a 12-month weight loss intervention using telephone-based counseling and community-situated physical activity in sedentary female breast and colorectal cancer survivors with BMI $\geq 25 \text{ kg/m}^2$, and 2) to estimate the effect size of the intervention on weight loss at 12 months. Other objectives were to measure changes in anthropometric measures, minutes spent per week in moderate-to-vigorous physical activity, dietary intake, metabolic biomarkers, and psychosocial factors, and the safety and acceptability of the intervention. Main outcome results are presented here.

METHODS

Participant recruitment and enrollment

From August 2012 to June 2014, participants were recruited from 9 selected SWOG sites representing academic medical centers and community clinical oncology programs (CCOPs) (Columbia University, New York, NY; Beaumont CCOP, Beaumont, MI; Kaiser Permanente Northern California, Oakland, CA; Loyola University, Maywood, IL; Puget Sound Oncology Consortium, Seattle, WA; University of Arizona, Tucson, AZ; University of Kansas, Kansas City, KS; Wichita CCOP, Wichita, KS; Greenville CCOP, Greenville, SC). Sites had a minimum of three Curves fitness centers within a 20-mile radius and had a track record of recruiting breast and/or colorectal cancer patients to trials. Of note, at the time of the study proposal, Curves International was the largest fitness franchise with over 10,000 fitness locations worldwide.

Participants were screened for the following eligibility criteria: female; previous diagnosis of Stage I to III invasive breast or colorectal cancer with no evidence of metastatic disease; 90 days to 7 years post-surgery, completed chemotherapy and/or radiation therapy (concurrent IV bisphosphonates, RANK ligand inhibitors and anti-hormonal therapies were permitted); post-menopausal; body mass index (BMI) $\geq 25 \text{ kg/m}^2$; currently sedentary (defined as <150 minutes of moderate-to-vigorous physical activity per week); Zubrod performance status of 0; no abnormal changes on a non-nuclear cardiovascular exercise stress test as measured by EKG; no evidence of uncontrolled hypertension; not diabetic, HgbA1C $\geq 8\%$; no history of prior weight loss surgery; no prior malignancy; not an active smoker in past 90 days; physician clearance to participate in weight loss and exercise trial; able to speak and read English; able and willing to participate in intervention activities and complete study assessments. IRB approval was obtained from all participating institutions and all participants provided written informed consent.

Baseline data collection

Clinical sites collected baseline data, including anthropometric measures (height, weight, hip and waist circumference using a standardized protocol and Gulick II (Country Technology, Inc., Gays Mills, WI) tape measure and fasting blood draws. Participants with a history of lymph node removal received participant education materials on "Exercise and

Lymphedema” and participants with ostomies received materials on “Exercising with an Ostomy.”

Next, participants were contacted by phone by the University of California San Diego (UC San Diego) Moores Cancer Center Diet and Physical Activity Shared Resource assessment team to collect data on the following: dietary intake via three 24-hour dietary recalls and a 7-day physical activity recall. The 24-hour dietary recall asked participants to recall the foods and beverages they consumed in the 24 hours prior to the interview.^{13,14} Self-reported physical activity was measured by 7-day physical activity recall to assess time spent on work and non-work-related moderate, hard, and very hard activities and strength and flexibility training for the 7 days prior to the interview.^{15,16} In addition, participants were asked to complete questionnaires online or by phone to collect data on demographics, cancer history, health conditions, and psychosocial measures.

Intervention

Once baseline data collection was complete, participants were contacted by the Moores UC San Diego Cancer Center Diet and Physical Activity Shared Resource telephone counseling team to begin the weight loss intervention motivational interviews. Participants were given an overall “reach” goal of losing 10% or more of their body weight over the 12-month period and patients received an individualized weight loss goal. Session 1 introduced participants to the study and participants were instructed to begin exercising at the pre-contracted Curves fitness center they identified as being convenient. Participants were mailed a study manual and a study pedometer.

Telephone behavioral counseling—Throughout the 12-month period, participants were paired with a lifestyle counselor with whom they had up to 14 40-minute behavioral counseling sessions. Using social cognitive theory¹⁷, the purpose of the calls were to establish a series of short-term goals, review performance on these goals to build self-efficacy and teach self-management skills.

Fitness center and physical activity—Participants were provided with 12-month memberships to a Curves fitness center, all of which had exercise equipment that provided exercise intensity data to users in real time. Fitness center staff completed safety training for working with breast and colorectal cancer survivors and provided a tailored fitness center orientation for participants. Participants were encouraged to complete the 30-minute circuit-based exercise program a minimum of three times per week, and a minimum of 60 minutes brisk walking per week, to reach a minimum of 150 minutes of moderate-to-vigorous physical activity per week.

Pedometer—Participants were provided with a pedometer (Curves TraQ Pedometer Model 370) to track their daily physical activity. Participants were encouraged to take 10,000 steps per day to increase overall physical activity.

Dietary modification—The overarching goal of the dietary modification program was to reduce caloric intake by 500 kcal/day, increase fruit/vegetable intake to 5 or more servings per day, limit daily calories from fat to <30%, and consume a diet high in whole grains, low

in saturated fats, sugars, and alcohol. The recommendations for healthy weight loss were based on guidelines issued by the National Heart Lung and Blood Institute and the American Institute for Cancer Research.^{18,19}

Newsletters—Participants received monthly emailed newsletters with health tips and motivational messages to encourage intervention adherence and trial retention.

Follow up data collection

At 6 and 12 months, participants returned for clinic visits to provide fasting morning blood draws and anthropometric measures and to assess adverse events, including lymphedema exacerbations. At 6 and 12 months, 24-hour dietary recalls and a 7-day physical activity recall were repeated. Participants were also asked to complete an exit interview at 12 months that assessed acceptability of and barriers to the intervention.

Statistical plan

The primary trial objective was to assess feasibility of this exercise and dietary change intervention within the SWOG cooperative group infrastructure, as assessed via trial accrual, intervention adherence, and trial retention. Analyses were conducted separately for breast and colorectal cancer survivors. The accrual goal was 25 participants for each cohort within 10 months after complete study activation at all participating sites. Adequate adherence to the intervention was defined as 68% (17) participants meeting both the diet criterion of increasing fruit and vegetable consumption by 1 full serving per day or reducing caloric intake by 100 kcal/day, and the exercise criterion of attending 2 Curves sessions per week for 36 of 52 weeks. Adequate retention to the intervention was defined as at least 17 participants providing anthropometric measures at 12 months. The effect size of the intervention on weight loss was measured by average weight loss at 12 months compared to baseline in each survivor cohort. We estimated the intervention's effect on self-reported physical activity, which was assessed via the 7-day physical activity recall and calculated as the average of total time spent per week on moderate, hard and very hard activities and strength and flexibility activities.

RESULTS

Recruitment

The CONSORT diagram (Figure 1) shows study recruitment and retention. In BC patients, accrual occurred in 10 months and 80% provided anthropometric measures at 12 months. In CRC patients, accrual occurred over 24 months and 87% provided anthropometric measures at 12 months. Among 25 evaluable BC and 23 evaluable CRC patients, median age at baseline was 57.3 years and 64.4 years, respectively, with median baseline BMI 37.2 kg/m² (range 27.7-54.6) and 31.8 kg/m² (range 26.4-48.7), respectively (Table 1). Sixty-four percent of BC patients had a history of Stage I breast cancer, and were a mean (SD) 2.2 (1.4) years from diagnosis, whereas 8% of CRC patients had a history of Stage I disease and were a mean (SD) 2.4 (1.7) years from diagnosis (Table 1).

Adherence and Behavior Change

Table 2 displays adherence to the pre-specified minimal adherence and behavior change goals to assess intervention feasibility. In BC patients, 60% met the diet goal (60% reduced caloric intake and 36% increased fruit/vegetable intake), 28% met the exercise goal, 28% met both diet and exercise goals, and 60% met at least one goal. In CRC patients, 61% met the diet goal (61% reduced caloric intake and 26% increased fruit/vegetable intake), 17% met the exercise goal, 13% met both diet and exercise goals, and 61% met at least one goal.

Table 3 displays data on specific changes in self-reported dietary intake and physical activity. On average, at 6 and 12 months, the BC group decreased total caloric intake by 555 and 502 kcal/day, respectively, compared to the CRC group which decreased total caloric intake by 226 kcal/day at 6 months and 452 kcal/day at 12 months, respectively. On average, women in the BC group reported increased moderate-to-vigorous physical activity by 199 minutes/week at 6 months and 242 minutes/week at 12 months, which was greater than the CRC group which reported an increase of 110 minutes/week of moderate-to-vigorous physical activity at 6 months and 70 minutes/week at 12 months.

Weight Loss

Study retention was adequate in both cohorts, with 80% (n=20) of BC participants and 87% (n=20) of CRC participants providing anthropometric measures at 12 months in each cohort. Among participants with 12-month data, average weight loss in the BC group was 7.6% (95% CI: -3.9%, 19.2%), with median weight loss of 7.1%. In the CRC group, average weight loss was 2.5% (95% CI: -8.2%, 13.3%), with median weight loss of 3.1% (Table 4 and Figure S1).

We examined weight loss by adherence to the minimal targeted behavior modification goals. In these participant subsets, confidence intervals were much wider due to small numbers. Among the 14 BC participants with 12-month data who adhered to the dietary goal, average weight loss at 12 months was 8.9% (95% CI: -3.7%, 21.5%). Among the 15 CRC participants who adhered to the dietary goal, average weight loss was 1.8% (95% CI: -9.8%, 13.4%).

Among the 7 BC participants who met the exercise adherence goal, average weight loss at 12 months was 9.9% (95% CI: -4.7%, 24.6%). Among the four CRC participants who met the exercise adherence goal, average weight loss was 4.8% (95% CI: -8.2%, 17.9%).

Metabolic Biomarkers

At 12 months, there were no statistically significant changes in either breast or colorectal cancer patients in HbA1c, fasting glucose or insulin (Table 4).

Adverse events

Participants were asked about lymphedema symptoms at baseline, 6 and 12 months. The BC group reported three exacerbations of previous cancer-related lymphedema and one new onset lymphedema, whereas the CRC group reported no lymphedema. One colorectal

participant reported Grade 3 neck and back pain. No serious adverse events were reported in either group (Table S1).

Acceptability and barriers to achieving diet and exercise goals

At study completion, 64% of BC survivors (n=16) and 65% of CRC survivors (n=15) responded to the exit interview (Table S2). Of the respondents, half of the participants considered the Curves program easy to access (50% in BC, 47% in CRC). Although the majority of the participants considered the Curves program helpful for increasing overall PA (88% in BC, 67% in CRC), BC patients compared to CRC patients reported greater perceived usefulness for increasing MVPA (94% in BC, 53% in CRC, $P=0.02$). The majority of participants reported that the brisk walking goal of 60 min/week was appropriate (88% in BC, 67% in CRC) and that the pedometer was helpful for increasing steps (81% in BC, 87% in CRC) and monitoring PA (88% in BC, 87% in CRC). However, nearly half of the participants reported difficulty going to Curves three or more times per week (44% in BC, 40% in CRC) and following the recommended meal plan (69% in BC, 33% in CRC). The primary reasons stated for non-adherence to the exercise goal included lack of time (31% in BC, 13% in CRC), feeling too tired (31% in BC, 13% in CRC), and health concerns (13% in BC, 7% in CRC). The main barriers to achieving diet change included lack of time to prepare/cook food (38% in BC, 13% in CRC), eating out frequently (31% in BC, 40% in CRC), and lack of family and social support (31% in BC, 27% in CRC).

DISCUSSION

In a single arm Phase II pilot and feasibility study of a 12-month weight loss intervention trial among female breast and colorectal cancer survivors recruited at a select set of academic and community institutions, we found different results between breast and colorectal cancer survivors. Though the recruitment and intervention methods were the same for both groups, the breast cancer survivors rapidly accrued to the trial in 10 months and achieved an average weight loss of 7.6%, whereas the colorectal cancer survivors accrued much more slowly and achieved an average weight loss of 2.5%. We conclude that this particular intervention is generally feasible in breast cancer survivors, but not in colorectal cancer survivors. Though participants in both groups did not meet the pre-specified adherence goals regarding fitness center attendance, they did substantially increase their overall physical activity.

Reasons for the differences between groups merit exploration. CRC patients have been difficult to enroll into exercise interventions. In the largest physical activity intervention among CRC patients to date, the Canadian Cancer Trials Group CO.21 (CHALLENGE) Trial is testing the effects of a structured three-year PA program on CRC outcomes.²⁰ However, in the first five years of this trial, only 273 of 962 participants were accrued to the trial.²¹ In our study, we were able to compare recruitment logs among two sites that kept detailed logs of recruitment screening (data not shown). Compared to breast cancer survivors, it was more difficult to recruit colorectal cancer survivors as they were older, had more uncontrolled comorbidities, were less likely to be overweight, and there were fewer numbers of patients available to be screened. To increase enrollment of CRC patients in

S1008, eligibility criteria were broadened during the trial to include CRC patients with managed comorbidities. Future studies should consider more inclusive eligibility criteria in order to more readily accrue CRC patients.

In terms of the differences in the effect size of the intervention on weight loss, our data suggest that colorectal cancer survivors were less likely to adhere to both the diet and the physical activity intervention. The magnitude of 7.6% weight loss observed in the breast cancer survivors at 12 months slightly exceeds weight loss observed in two other recently published weight loss trials among breast cancer survivors.^{22,23} The LISA trial was a multicenter randomized controlled trial of a Diabetes Prevention Program-based²⁴ 24 month telephone-based weight loss intervention among postmenopausal women with breast cancer receiving letrozole (n=338).²² Though the LISA trial was designed to deliver more telephone counseling sessions compared to S1008 during the first 12 months (29 calls in LISA vs. 14 calls in S1008), the LISA trial intervention arm achieved a slightly smaller effect on average weight reduction (5.5% in LISA vs. 7.1% in S1008). The ENERGY trial was a 24 month multicenter randomized controlled trial of a weight loss intervention for overweight and obese breast cancer survivors (n=692).²³ At 12 months, the ENERGY trial achieved a 6.0% (SEM 0.4%) reduction in weight from baseline.

There are two possible explanations for why the women in S1008 lost slightly more weight than those in the LISA and ENERGY trials. First, because S1008 baseline mean BMI exceeded that of LISA and ENERGY participants (mean BMI 36.5 kg/m² vs. 31.4 kg/m² and 31.6 kg/m², respectively), it is possible that S1008 participants were able to lose weight more quickly. Second, the S1008 intervention itself may have been more effective at achieving weight loss, possibly due to the gym membership and high increases in physical activity. Nevertheless, the weight loss achieved in S1008, LISA and ENERGY were similar, illustrating that there are multiple avenues to achieving clinically meaningful weight loss in cancer survivors.

Prior clinical trials have shown resistance and aerobic exercise to be safe in BC patients and to reduce lymphedema symptoms.^{25–27} Although the S1008 intervention was generally safe, one (4%) BC participant developed lymphedema and three (12%) reported exacerbations of lymphedema. Study participants may have been at elevated risk of lymphedema due to surgery and having more than one lymph node removed, which are known risk factors for lymphedema.²⁸ However, in our trial, the occurrence of lymphedema or its exacerbation was less frequent than estimates from previous exercise intervention for lymphedema and observational studies of BC survivors, which estimate that 7–26% of breast cancer survivors will develop lymphedema over the 2 years following surgery.^{25,26,28–31}

The primary novel aspect of the S1008 intervention was that it incorporated a network of community-situated fitness centers into the model, allowing women to participate in a structured exercise circuit in a woman-centric environment. The majority of other weight loss interventions make use of home-based exercise, which often consists of walking and strength training exercises. However, head-to-head comparisons are needed to test whether home-based or fitness center-based physical activity programs are more effective at achieving and maintaining weight loss.

A strength of this study is that we tested a community-situated physical activity resource provided by a national chain, which could allow for larger scale implementation of such an intervention. The fitness center program was priced at approximately \$50/month, which is a negligible cost in oncology clinical care. The study design allows comparison of the effects of an intervention across two different populations of sedentary female breast and colorectal cancer survivors with BMI ≥ 25 kg/m². Provision of a community fitness center membership and telephone-based counseling produced better results in breast cancer survivors, compared to colon cancer survivors. This difference may have been due to underlying differences in patient clinical characteristics (e.g., colorectal cancer patients were older and had more comorbidities compared to breast cancer patients) or to differences in patient preferences (e.g., colorectal cancer patients found the Curves program less helpful in increasing physical activity compared to the breast cancer patients). An additional strength was that the trial made use of the existing NCI cooperative group infrastructure. The primary limitation was the small sample size, but that was by design so that we could pilot the intervention and determine the feasibility of conducting a future intervention. An additional limitation is the use of self-reported diet and physical activity measures, but the weight change was based on objective measurements. Finally, although the weight loss program demonstrated good acceptability among BC and CRC patients, the data were only collected from participants who completed the 12 months follow-up and therefore may be subject to selection bias.

The American Society for Clinical Oncology has launched a new initiative focused on addressing the risks associated with obesity in cancer survivors³², which highlights the growing importance of this field of research in cancer prevention and control. In this pilot and feasibility trial, we showed that a community-based fitness program coupled with telephone behavioral counseling was effective at achieving and maintaining clinically significant weight loss at 12 months in female breast cancer, but not colorectal cancer survivors. This model could have important public health implications because the model could be widely disseminated. Trials are needed to investigate the effects of weight loss interventions on survival outcomes, and the Breast Cancer Weight Loss Study (BWEL) trial is currently underway (NCT02750826). The BWEL Study is testing whether post-diagnosis weight loss will result in improved breast cancer recurrence rates in women with early stage breast cancer (n=3,136). Trials are needed to identify effective weight loss and behavior interventions in colorectal cancer survivors.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Study Importance Questions

What is already known about this subject?

- Higher BMI at the time of diagnosis is associated with poorer prognosis for breast cancer (BC) and colorectal cancer (CRC) survivors.
- Previous studies demonstrated that home-based weight loss interventions may effectively reduce body weight in BC survivors.

What does your study add?

- Our study demonstrated feasibility to recruit and retain female BC survivors in a cooperative group weight loss trial using community-situated physical activity and telephone-based counseling to improve diet and physical activity.
- BC survivors increased physical activity and achieved clinically meaningful weight loss over 12 months.
- The intervention was less effective for female CRC survivors.

Figure 1.

Phase II feasibility study of a physical activity and dietary change weight loss intervention in breast and colorectal cancer survivors (SWOG S1008) - consort diagram

Table 1

Baseline population characteristics of cancer survivors enrolled in SWOG S1008

	Breast (n=25)		Colorectal (n=23)	
	n	%	n	%
DEMOGRAPHIC CHARACTERISTICS				
Age at Enrollment	median: 57	range: 32-70	median: 64	range: 50-78
Education				
High school or less	1	4	2	9
College or some college	16	64	15	65
Postgraduate school or degree	8	32	6	26
Marital Status				
Married or living with a partner	17	68	17	74
Divorced/widowed	6	24	5	22
Never married	2	8	1	4
Employment				
Employed	17	68	11	48
Retired (not due to health)	3	12	8	35
Disabled and/or retired because of health	1	4	1	4
Annual Income				
\$0-\$60,000	7	28	8	35
\$60,001 - \$100,000	8	32	7	30
More than \$100,001	8	32	4	17
Race				
Black or African American	3	12	1	4
White	21	84	20	87
Hispanic	1	4	1	4
Other	0	0	1	4
CLINICAL CHARACTERISTICS				
Time since diagnosis (years)	mean: 2.2	range: 0.3 - 6.9	mean: 2.4	range: 0.6 - 6.9
Body mass index (kg/m²)	median: 37.2	range: 27.7-54.6	median: 31.8	range: 26.4-48.7
Stage				
I	16	64	2	9
II	5	20	11	48
III	4	16	10	43
Node				
positive	5	20	10	43
negative	20	80	13	57
Number of lymph nodes removed	mean: 6.8, median: 3	range: 0-29	mean 19.6, median 17	range: 0-57
Tumor Laterality (for breast only)				
left	14	56	N/A	-

	Breast (n=25)		Colorectal (n=23)	
	n	%	n	%
right	9	36	N/A	-
bilateral	2	8	N/A	-
History of cancer-related lymphedema	4	16	1	4
Prior treatment related to cancer				
Chemotherapy	14	56	14	58
Radiotherapy	18	72	2	8
Hormonal therapy	17	68	0	0
Surgery	25	100	24	100
Other	2	8	0	0
History of diabetes, pre-diabetes, and/or metabolic syndrome				
Yes	5	20	3	13
No	20	80	20	87
Number of comorbidities *	mean: 1.7	range: 0 - 10	mean: 2.2	range: 0 -10

Note:

Number of missing values was not reported in this table.

* Comorbid conditions collected included history of smoking, renal insufficiency, abnormal pulmonary function, hypertension, heart disease, hearing impairment, visual impairment, deformity or orthopedic impairment, diminished mental capacity/neurologic impairment/dementia, arthritis, and HIV/AIDS

Table 2

Adherence to 12 month weight loss intervention

	Breast Cohort (n=25)		Colorectal Cohort (n=23)	
	N	%	N	%
Dietary Adherence *				
Adherent	15	60	14	61
Non-adherent: reported but did not meet criteria	1	4	2	9
Non-adherent: not reported	9	36	7	30
Reduce Caloric Intake				
Adherent	15	60	14	61
Non-adherent: reported but did not meet criteria	1	4	2	9
Non-adherent: not reported	9	36	7	30
Increase in fruit and vegetable				
Adherent	9	36	6	26
Non-adherent: reported but did not meet criteria	7	28	10	43
Non-adherent: not reported	9	36	7	30
Exercise Adherence **				
Adherent	7	28	4	17
Non-adherent	18	72	19	83
Adherence to Both Diet and Exercise Interventions ***				
Yes	7	28	3	13
No	18	72	20	87
Adherence to at least one diet and/or exercise marker of adherence				
Yes	15	56	15	65
No	10	44	8	35

* Defined as a reduction in caloric intake by 100 kcal/day or increase of fruit and vegetable consumption by 1 serving per day

** Attended 2 Curves sessions per week for a minimum of 36 weeks

*** Adherent to both the diet and physical activity as defined above

Change in dietary intake and physical activity during 12 month weight loss intervention among SWOG S1008 participants

Table 3

	Baseline			6 month			12 month			
	n	Mean	n	Mean	Mean absolute change from baseline	P value *	n	Mean	Mean absolute change from baseline	P value *
Breast Cohort										
DIETARY INTAKE										
Calories, kcal	25	1850.9	19	1416.2	-554.8	<.001	16	1429.6	-501.7	<.001
Fruit, servings **	25	1.5	19	1.9	0.4	.34	16	2.5	0.8	.14
Vegetables, servings	25	2.4	19	3.3	0.7	.09	16	3.5	0.8	.15
Total Fruits and Vegetables, servings	25	3.9	19	5.3	1.1	.04	16	6.0	1.5	.04
Fiber, gm	25	21.1	19	21.8	-0.4	.82	16	21.0	-2.3	.32
% Kcal from Fat	25	37.4	19	32.5	-6.0	<.001	16	31.9	-6.6	.001
% Kcal from Carbs	25	47.2	19	46.5	0.7	.68	16	47.6	2.2	.28
% Kcal from Protein	25	17.2	19	23.0	5.6	.001	16	22.6	4.9	<.001
% Kcal from Saturated Fat	25	11.6	19	9.0	-2.8	.003	16	9.5	-2.5	.001
% Kcal from Trans Fatty Acid	25	1.2	19	0.8	-0.4	.01	16	0.8	-0.3	.004
% Kcal from Alcohol	25	0.8	19	1.0	0.0	.92	16	0.7	-0.4	.49
PHYSICAL ACTIVITY										
Moderate Activity Minutes ***	25	124.2	18	260.2	161.8	.003	16	285.4	178.2	<.001
Work	25	3.0	18	23.3	20.8	.21	16	0.0	-2.8	.33
Leisure	25	121.2	18	236.8	140.9	.008	16	285.4	181.1	<.001
Hard Activity Minutes	25	2.4	18	10.8	9.2	.42	15	18.1	16.2	.15
Work	25	0.0	18	7.5	7.5	.33	16	0.0	0.0	-
Leisure	25	2.4	18	3.3	1.7	.67	16	18.1	16.2	.45
Very Hard Activity Minutes	25	1.8	18	0.0	-2.5	.33	16	4.4	1.5	.78
Work	25	0.0	18	0.0	0.0	-	16	0.0	0.0	-
Leisure	25	1.8	18	0.0	-2.5	.33	16	4.4	1.5	.78
Strength Minutes	25	2.4	18	26.4	23.1	.02	16	42.8	39.1	.02
Flexibility Minutes	25	0.0	18	7.2	7.2	.03	16	6.6	6.6	.13
Total Minutes of Physical Activity	25	130.8	18	304.6	198.7	.001	16	357.2	241.6	<.001
Colorectal Cohort										

	Baseline			6 month			12 month			
	n	Mean	n	Mean	Mean absolute change from baseline	P value*	n	Mean	Mean absolute change from baseline	P value*
DIETARY INTAKE										
Calories, kcal	23	1515.7	19	1342.2	-225.8	.06	16	1162.1	-451.7	.002
Fruit, servings**	23	1.8	19	1.9	0.1	.80	16	1.9	-0.1	.86
Vegetables, servings	23	2.2	19	3.2	0.9	.02	16	3.2	0.9	.16
Total Fruits and Vegetables, servings	23	4.3	19	5.4	1.0	.05	16	5.1	1.0	.34
Fiber, gm	23	17.5	19	18.2	-0.3	.86	16	17.6	-1.0	.64
% Kcal from Fat	23	34.0	19	31.3	-3.4	.10	16	32.5	-2.6	.09
% Kcal from Carbs	23	48.2	19	49.5	1.3	.55	16	46.5	-2.1	.24
% Kcal from Protein	23	18.4	19	20.1	2.6	.07	16	21.7	4.6	.02
% Kcal from Saturated Fat	23	10.4	19	9.1	-1.6	.03	16	9.6	-1.4	.10
% Kcal from Trans Fatty Acid	23	1.0	19	0.8	-0.2	.15	16	0.9	-0.1	.47
% Kcal from Alcohol	23	1.8	19	1.8	-0.3	.38	16	2.3	0.5	.57
PHYSICAL ACTIVITY										
Moderate Activity Minutes***	23	141.1	18	211.6	73.4	.06	16	195.8	59.0	.36
Work	23	6.1	17	17.5	9.7	.52	15	4.7	-4.1	.65
Leisure	23	135.0	18	194.1	63.7	.06	16	191.1	63.1	.33
Hard Activity Minutes***	23	14.3	18	13.3	-5.0	.81	16	25.3	4.7	.87
Work	23	14.3	18	3.3	-15.0	.44	16	3.8	-16.9	.44
Leisure	23	0.0	18	10.0	10.0	.11	15	21.6	21.6	.18
Very Hard Activity Minutes***	23	0.0	18	0.0	0.0	-	16	0.0	0.0	-
Work	23	0.0	18	0.0	0.0	-	16	0.0	0.0	-
Leisure	23	0.0	18	0.0	0.0	-	16	0.0	0.0	-
Strength Minutes	23	7.2	18	44.4	35.3	.14	16	16.9	6.6	.62
Flexibility Minutes	23	0.0	18	6.4	6.4	.12	16	0.0	0.0	-
Total Minutes of Physical Activity	23	162.6	18	275.8	110.1	.009	16	237.9	70.3	.15

* P-values calculated from paired t-tests comparing baseline to 6 and 12 month values

** Fruit excluded fruit juice

*** Moderate activity is similar to how people feel when they are walking at a normal pace; the very hard activity is similar to how people feel when they are running; the hard activity refers to intensity falls in between moderate and very hard activities.

Table 4.
Change in anthropometric and metabolic markers during 12 month weight loss intervention among SWOG S1008 participants

	Baseline				6 month			12 month			
	N	Mean	Range	N	Mean	Mean absolute change from baseline	P value*	N	Mean	Mean absolute change from baseline	P value*
Breast											
Weight (kg)	25	98.1	72.5–128.2	22	93.2	5.5 (5.5%)	<.01	20	92.5	7.8 (7.6%)	<.01
BMI (kg/m ²)	25	36.5	27.7–54.6	22	35.0	1.8	<.01	20	34.3	2.7	<.01
Waist Circumference (cm)	25	109.9	90.0–137.0	21	104.6	5.6	<.01	16	105.0	6.3	<.01
Hip Circumference (cm)	25	123.6	101.8–160.0	21	120.8	4.0	<.01	16	117.2	7.7	<.01
HbA1c (%)	20	5.7	5.2–6.7	18	5.8	0.1	.68	10	5.6	−0.2	.47
Fasting glucose (mg/dL)	20	98.8	83.0–160.0	17	100.4	2.5	.78	10	102.0	10.5	.63
Fasting insulin (mIU/L)	20	20.8	6.0–61.2	17	40.4	20.8	.35	10	34.9	18.8	.54
Colorectal											
Weight (kg)	23	85.4	61.9–127.0	21	82.2	2.5 (2.8%)	<.01	20	81.9	2.1 (2.5%)	.05
BMI (kg/m ²)	23	32.7	26.4–48.7	21	31.8	0.9	<.01	20	32.2	0.3	.55
Waist Circumference (cm)	23	101.4	77.0–133.0	19	98.4	1.5	.19	19	98.7	1.8	.17
Hip Circumference (cm)	23	116.0	98.5–150.0	19	112.2	2.4	.02	19	113.5	2.7	.08
HbA1c (%)	18	5.7	5.2–6.9	15	5.9	0.0	.38	9	5.8	−0.1	.84
Fasting glucose (mg/dL)	17	103.6	77.0–158.0	15	103.9	0.8	.97	7	109.1	12.0	.75
Fasting insulin (mIU/L)	17	20.2	6.3–69.4	15	21.3	2.4	.89	7	22.8	4.5	.74

*P-values calculated from match paired t-tests comparing baseline to 6 and 12 month values

Abbreviations: SWOG, Southwest Oncology Group; BMI, body mass index; HbA1c, hemoglobin A1c