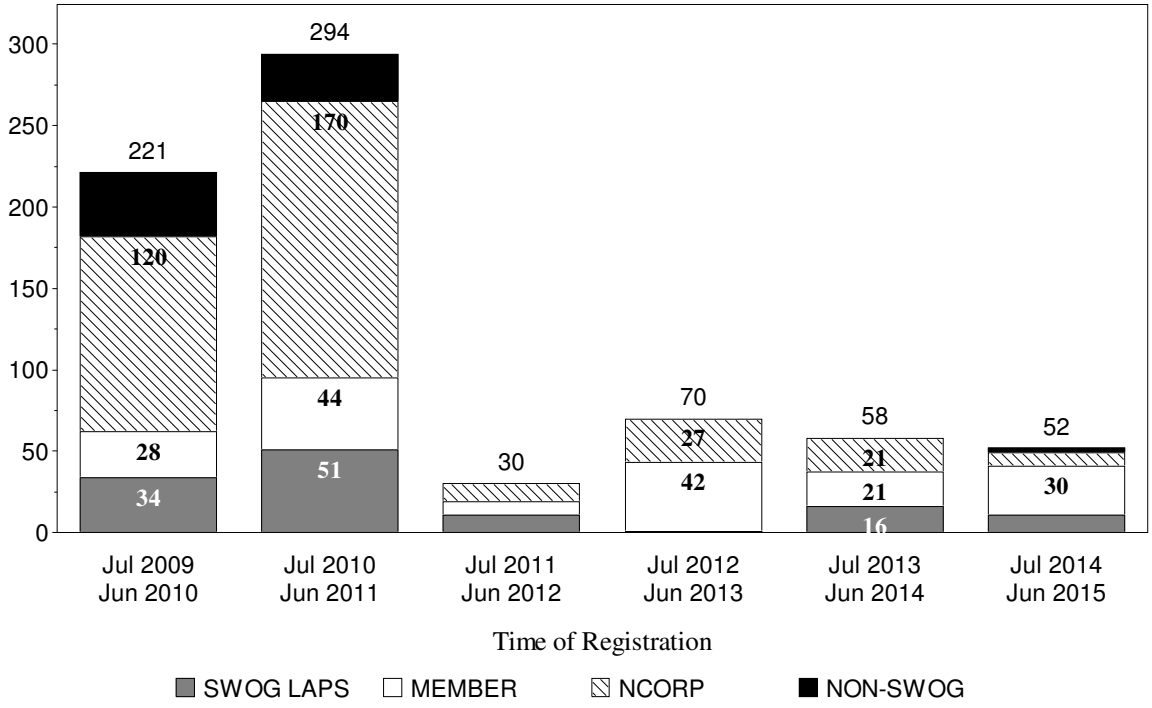
CANCER SURVIVORSHIP COMMITTEE

CONTENTS

Patient Registrations to Studies

By 12 Month Intervals
CANCER SURVIVORSHIP COMMITTEE



Screening registrations and registrations to Biologic only studies are excluded

Patient Registrations by Study and Arm

CANCER SURVIVORSHIP COMMITTEE

	Jan 2015 Jun 2015	Jul 2014 Dec 2014	Jan 2014 Jun 2014	All Patients
S1008 Surv, Breast/Colon, Curves Pilot				
Initial registration				
Intervention	0	0	11	50
S1316 Compar. Effectiv. Trial for MBO				
Registration				
Surgery NONRAND	2	0	0	2
NonSurgical Management NONRAND	1	0	0	1
	3	0	0	3
C70807 Pros, MEAL Study*				
Endorsed Study				
Total Registrations	23	26	23	157

* For non-SWOG coordinated studies only SWOG registrations are shown.

S1008 Phase II

Feasibility Study of a Physical Activity and Dietary Change Weight Loss Intervention in Breast and Colorectal Cancer Survivors, Phase II

Study Chairs:
H Greenlee, D Hershman

Statisticians:
D Lew, J Unger

Data Coordinator:
D Marrah

Date Activated:
03/01/2012

Date Closed:
07/01/2014

Objectives

To determine the feasibility of a 12-month community-situated combined physical activity and dietary change weight loss intervention in overweight and sedentary female breast and colorectal cancer survivors recruited via SWOG. Feasibility will be assessed based on study accrual, intervention adherence, and study retention. Analyses will be conducted separately for breast and colorectal cancer survivors.

To estimate the effect size of the intervention on weight loss at 12 months.

To measure changes from baseline to 6 and 12 months in anthropometric measures (body mass index [BMI], waist and hip circumference) and changes from baseline to 12 months in body composition (% body fat as assessed by DXA scan).

To measure changes from baseline to 6 and 12 months in minutes spent per week in moderate-to-vigorous aerobic activity using Curves® attendance records and a 7-day physical activity assessment.

To measure changes from baseline to 6 and 12 months in self-reported dietary intake via three separate 24-hour diet recalls at each time point.

To measure changes from baseline to 6 and 12 months in dietary intake of carotenoids via serum carotenoid measures.

To measure changes from baseline to 6 and 12 months in metabolic and hormonal biomarkers associated with breast and colorectal cancer recurrence risk (fasting insulin, fasting glucose, hemoglobin A1C, bioavailable estradiol, free testosterone, and adiponectin).

To assess changes from baseline to 6 and 12 months in anxiety, depression, fatigue, sleep, satisfaction with social roles, pain and physical function using the PROMIS-43.

To assess changes from baseline to 6 and 12 months in perceived benefit of dietary change, physical activity and weight loss after a cancer diagnosis.

To assess the diversity of subjects who enroll and complete the intervention.

To assess baseline predictors (medical history, health behaviors, quality of life) of subjects who adhere to and complete the intervention.

To assess the safety of the Curves® fitness centers for this population by assessing self-reported changes in lymphedema and any injuries as measured at 6 and 12 months.

To assess the availability and acceptability of the Curves® fitness centers at 12 months.

To assess the acceptability of the dietary change component of the intervention at 12 months.

To explore changes in DNA methylation.

To assess the intervention and study process via open-ended interviews with SWOG sites and Curves® franchises.

To measure changes in anthropometric measures and assess feasibility of extended follow-up at 24 and 36 months.

Patient Population

Participants must be women with a previous diagnosis of invasive breast cancer or colorectal cancer, Stage I, II, or III, with no evidence of metastatic disease (M0). Participants must have no evidence of disease at the time of registration and no history of metastases. Participants must be post-menopausal as defined in the protocol.

Participants must be 90 days to 7 years post-surgery, chemotherapy, and radiation therapy. Concurrent cytotoxic therapies, including Herceptin, are not allowed among breast cancer patients. Other concurrent therapies are allowed among breast cancer patients, including IV bisphosphonates (e.g., Zometa), RANK ligand inhibitors (e.g., Xgeva, Prolia), and anti-hormonal therapies (e.g., aromatase inhibitors). Participants must not have had weight loss surgery.

Participants must be considered sedentary as defined in the protocol, have a BMI $\geq$ 25 kg/m2 and a Zubrod performance status of 0. Participants must have no abnormal changes on cardiovascular exercise stress test as measured by EKG. Participants must not be active smokers or have evidence of uncontrolled hypertension. Participants with diabetes, pre-diabetes, and/or metabolic syndrome must have HgbA1C $\leq$ 8. Participants must be willing and able to attend a Curves® fitness center at least three times per week for 12 months and agree to participate in the behavioral counseling sessions and telephone interviews. Participants must be willing to submit blood samples for biomarkers. Participants must have physician clearance to participate, regular access to the internet, a home phone or cell phone, and be able to understand, speak and read English.

Stratification/Descriptive Factors

Participants will be stratified at time of registration by type of cancer: breast vs colorectal.

Accrual Goals

The accrual goal is 25 eligible breast cancer survivors and 25 eligible colorectal cancer survivors.

Summary Statement

This study was activated March 1, 2012, to limited institutions and enrolled 50 participants prior to closure on July 1, 2014: 26 breast cancer survivors and 24 colorectal cancer survivors. One participant who was removed from protocol prior to starting study intervention is not analyzable and was replaced within the breast cancer survivor cohort. Study results for the other 25 breast cancer survivors were presented at ASCO in June 2015 with the following results:

Among 25 evaluable participants, median age was 57.3 years with median BMI 37.5 kg/m^2 (range 27.7-54.6), 64% Stage I, and median 2.1 years from diagnosis. Accrual occurred in 10 months, 80% of participants provided anthropometric measures at 12 months, 96% of participants met the diet goal, and 28% of participants met the exercise goal. Thus feasibility goals were met, with the exception of exercise adherence as defined a priori. At 12 months, average weight loss was 7.6% (95% CI -3.9%, 19.2%) with median weight loss of 7.1%. The conclusion was that it is feasible to recruit and retain breast cancer survivors in a multicenter weight loss trial using dietary change plus physical activity to achieve clinically meaningful weight loss over 12 months.

Registration by Institution

Institutions	Total Reg	Institutions	Total Reg
Kaiser Vallejo NCORP	20	Beaumont NCORP	3
Loyola University	8	PCRC NCORP	3
Kansas, U of	6	Arizona MC, U of	1
Greenville NCORP	4	Columbia MU-NCORP	1
Wichita NCORP	4	**Total (9 Institutions)**	**50**

Registration, Eligibility, and Evaluability

Classified by Disease Cohort
Data as of September 1, 2015

	TOTAL	Breast	Colorectal
NUMBER REGISTERED	50	26	24
ELIGIBLE	50	26	24
Not Analyzable	1	1	0
ADVERSE EVENT ASSESSMENT			
Evaluable	46	24	22
Not Evaluable	3	1	2

Patient Characteristics

Classified by Disease Cohort
Data as of September 1, 2015

	Breast (n=25)		Colorectal (n=24)	
AGE				
Median	57.3		64.3	
Minimum	32.9		50.5	
Maximum	70.9		78.2	
HISPANIC				
Yes	1	4%	2	8%
No	24	96%	22	92%
RACE				
White	22	88%	19	79%
Black	3	12%	2	8%
Asian	0	0%	1	4%
Native American	0	0%	1	4%
Unknown	0	0%	1	4%
TYPE OF CANCER				
Breast	25	100%	0	0%
Colorectal	0	0%	24	100%

Treatment Summary

Classified by Disease Cohort

Data as of September 1, 2015

	TOTAL	Breast	Colorectal
NUMBER ON PROTOCOL TREATMENT	15	0	15
NUMBER OFF PROTOCOL TREATMENT	34	25	9
REASON OFF TREATMENT			
Treatment completed as planned	12	7	5
Adverse Event or side effects	0	0	0
Refusal unrelated to adverse event	8	6	2
Progression/relapse	1	0	1
Death	0	0	0
Other - not protocol specified	1	1	0
Reason under review	12	11	1
MAJOR PROTOCOL DEVIATIONS	0	0	0

S1316 Pilot

Coordinating Group: SWOG

Prospective Comparative Effectiveness Trial For Malignant Bowel Obstruction

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Participants:
SWOG, Alliance

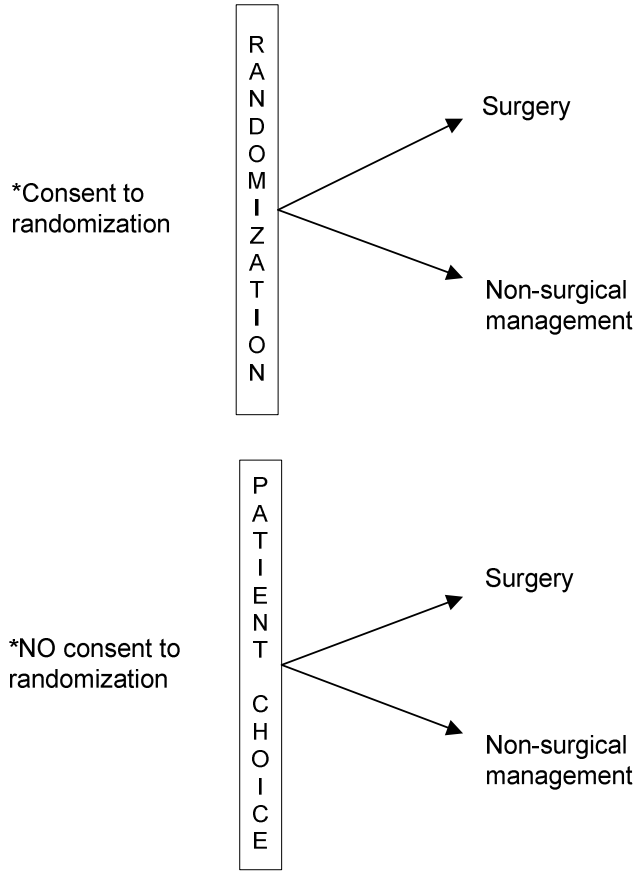
Date Activated:
03/09/2015

Study Chairs:
R Krouse, B Bagwell, A Abernethy (Alliance)

Statisticians:
G Anderson, K Arnold

Data Coordinator:
R Topacio

SCHEMA



*Patients will be enrolled into either the randomized or patient choice portion, not both

Objectives

To compare quality of life, as assessed by the number of days alive and residing outside of the hospital within the first 91 days (13 weeks) after registration, among patients with malignant bowel obstruction (MBO) who receive surgical intervention and similar patients treated non-surgically.

To explore whether there are differences in other health related quality of life (HRQOL) factors of particular interest in this population, including ability to eat, days with nasogastric tube, development of nausea, days of intravenous hydration, days eating solid foods and days drinking that are different for patients with MBO who receive surgical intervention as compared to non-surgical intervention.

To explore whether overall survival is different for patients with MBO who receive surgical intervention as compared to non-surgical intervention. To estimate the effects of surgical versus non-surgical management on quality of life after adjustment for non-adherence to initially assigned/chosen treatment.

To explore whether there are clinical factors (e.g., ascites, albumin, carcinomatosis) that predict better quality of life outcomes for patients with MBO who receive surgical intervention as compared to non-surgical intervention.

Patient Population

Patients must have clinical evidence of a small bowel obstruction (via history, physical, and radiographic examination) distal to ligament of Treitz, with radiographic confirmation prior to registration. Patients must have intra-abdominal primary cancer with incurable disease. Patients may still have primary tumor as long as it is not a primary large bowel obstruction from colorectal cancer. Patients must not have signs of bowel perforation necessitating surgery or "acute" abdomen as evidenced by peritonitis on physical exam within two days prior to registration.

Patients must be registered to the study within three days after surgical consult for MBO and prior to any treatment (surgical or non-surgical) for MBO. Somatostatin analogues may be used prior to registration if that use is limited to not more than the two days just prior to registration.

Patients must be able to tolerate a major surgical procedure based on clinical evaluation, status of their cancer, and any other underlying medical problems. A member of the patient's surgical team must indicate equipoise for the benefit of the surgical treatment for MBO. Patients must be 18 years or older and have Zubrod performance status of 0-2 within seven days prior to hospitalization. Serum albumin must be planned to be collected after hospital admission, but prior to treatment. History and physical must be obtained within three days prior to registration. Patients must be able to complete the study questionnaires in English or Spanish.

Stratification/Descriptive Factors

Participant randomization will be stratified by primary tumor type: colorectal cancer vs. ovarian cancer vs. other cancer.

Accrual Goals

A total of 200 patients will be accrued with a target of at least 50 patients in the randomized component.

Summary Statement

This study activated on March 9, 2015, to limited institutions. As of June 30, 2015, 3 patients have been registered, all to the patient choice portion.

Registration by Institution

Registrations ending June 30, 2015

Institutions	Total Reg
Alliance	3
Total (1 Institutions)	**3**

C70807 Phase III SWOG Supported CTSU Study

Coordinating Group: Alliance

The Men's Eating and Living (MEAL) Study: A Randomized Trial of Diet to Alter Disease Progression in Prostate Cancer Patients on Active Surveillance

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Participants:
Alliance, SWOG, CTSU

Date Activated:
01/21/2011

Study Chairs:
J Parsons (Alliance), P Van Veldhuizen (SWOG)

Date Closed:
08/14/2015

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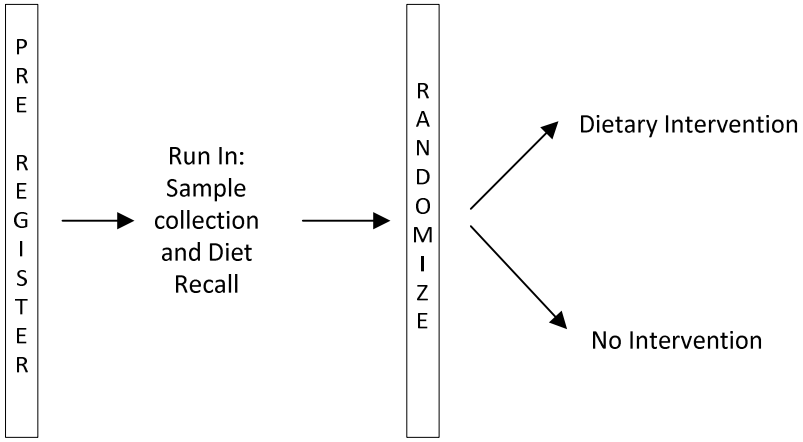

Objectives

To determine if a telephone-based dietary intervention compared to no intervention will decrease clinical progression in active surveillance (AS) patients.

To compare the incidence of active treatment (surgery, irradiation, local ablation, or androgen deprivation) in AS patients receiving dietary intervention compared to no intervention.

To compare prostate cancer-related anxiety in AS patients receiving dietary intervention compared to no intervention.

To compare health-related quality of life in AS patients receiving dietary intervention compared to no intervention.

Patient Population

Patients must have biopsy-proven (consisting of 10 or more tissue cores) adenocarcinoma of the prostate diagnosed within 24 months prior to pre-registration, with less than 25% of the cores positive for cancer, and no more than 50% of any one biopsy tissue core positive for cancer. Patients must have clinical stage less than or equal to T2a and must not have distant metastases. For men less than or equal to 70 years old, biopsy Gleason score must be less than or equal to 6. For men greater than 70 years old, biopsy Gleason score must by less than or equal to 7 (3 + 4). Baseline serum PSA must be less than 10 ng/ml.

Patients must not have received prior treatment for prostate cancer by surgery, irradiation, local ablative, or androgen deprivation therapy. Patients must not have received treatment with 5-alpha reductase inhibitors within 90 days prior to pre-registration.

Patients must be men aged 50 to 80 years and be able to read and comprehend English language text and be able to understand spoken English over the phone. Patients must not be currently taking coumadin or vitamin supplements including lycopene and beta-carotene.

Patients are eligible for randomization after successful completion of three 24-hour dietary recalls during the run-in period, provided they are not consuming six or more servings per day of fruits and vegetables (not including juices).

Stratification/Descriptive Factors

Patient randomization will be stratified according to the following factors: (1) age: men ≤ 70 years vs men >70 years; (2) race: Black or African American vs other; and (3) baseline prostate biopsy: 0-12 months prior to pre-registration vs >12-24 months prior to pre-registration.

Accrual Goals

The accrual goal is 464 patients (232 per arm). Interim analysis will be performed after 80 patients progress or complete the two years of follow-up and then every six months until full information.

Summary Statement

For the current status of this study, please refer to the Genitourinary chapter.