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Was Race a Factor in the Outcomes of the Women's Health Eating and Living Study?

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Abstract

BACKGROUND—The purpose of this study was to determine whether women participating in the Women's Healthy Eating and Living (WHEL) Study, exhibited similar dietary changes, second breast cancer events, and overall survival regardless of race/ethnicity.

METHODS—This secondary analysis used data from 3013 women self-identifying as Asian Americans, African American, Hispanic, or white and who were randomly assigned to a dietary intervention or comparison group. Changes in dietary intake over time by race/ethnicity and intervention status were examined using linear mixed-effects models. Cox proportional hazards models were used to examine the effects of the intervention on the occurrence of second breast cancer events and overall survival. Statistical tests were 2-sided.

RESULTS—African Americans and Hispanics consumed significantly more calories from fat (+3.2%) and less fruit (−0.7 servings/day) than Asians and whites at baseline (all $P < 0.01$). Overall, intervention participants significantly improved their dietary pattern from baseline to the end of year 1: reducing calories from fat by 4.9% and increasing intake of fiber (+6.6 grams/day), fruit (+1.1 servings/day), and vegetables (+1.6 servings/day) (all $P < 0.05$). Despite improvements in the overall dietary pattern of these survivors, the intervention did not significantly influence second breast cancer events and overall survival.

CONCLUSIONS—Overall, all racial groups significantly improved their dietary pattern over time, but the maintenance of these behaviors were lower among African American women. More research and larger minority samples are needed to determine the specific factors that improve breast cancer-specific outcomes in diverse populations of survivors.

Keywords

breast cancer; diet; ethnicity; race; randomized controlled trial; survival

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INTRODUCTION

Systematic review studies have proposed that a healthy living for cancer survivors that includes a diet low in fat and high in fiber, fruits, and vegetables may improve health-related quality of life, prevent disease recurrence, and improve disease-specific and overall mortality.^{1–5} Adhering to these behaviors is especially important for minority survivors, whose risk of recurrence and comorbid conditions is greater than that of white survivors.^{6, 7} Therefore, interventions that promote adopting and maintaining healthy lifestyle behaviors may hold promise for improving the health and well-being of minority survivors.^{2, 5, 8} However, limited research exists on the health behaviors of minority survivors, and minorities are underrepresented in clinical trials promoting health behaviors.^{9, 10}

The Women's Healthy Eating and Living (WHEL) Study was designed to determine whether a diet low in fat and high in fruits, vegetables, and fiber could improve recurrence-free and overall survival.¹¹ Results from the WHEL Study suggested that an intensive telephone counseling intervention could improve diet dramatically; however, this significant improvement in diet did not translate into meaningful improvements in recurrence-free and overall survival.¹² On the basis of these findings, we performed a secondary analysis to determine whether the intervention resulted in similar dietary changes, regardless of race/ethnicity and whether the impact of the intervention on second breast cancer events and overall survival differed by race/ethnicity.

PATIENTS AND METHODS

Study Population

In the WHEL Study, breast cancer survivors were recruited between 1995 and 2000 from clinical sites in California, Arizona, Oregon, and Texas; the institutional review boards at all the sites approved the WHEL Study protocols. Eligible patients had been diagnosed with stage I–IIIA breast cancer within 4 years of study entry; were 18–70 years old at diagnosis; had completed treatment with no evidence of recurrent disease; and had not been diagnosed with any other cancers within 10 years of study enrollment. Additional WHEL Study inclusion and exclusion criteria have been reported previously.¹¹ WHEL Study participants who self-reported their ethnicity as Asian American, African American, Hispanic, or white were included in the current study. The CONSORT diagram is depicted in Figure 1.

Study Design and Randomization

The WHEL Study was a multisite, randomized controlled trial designed to investigate the effects of a low-fat diet high in fiber, fruits, and vegetables on disease recurrence and overall survival in breast cancer survivors. Study participants were block-randomized to an intervention or comparison group that was stratified by clinical site, age, and tumor stage. Decisions about excluding patients from the study after randomization were made by an independent data and safety monitoring committee.¹¹

Dietary Intervention

The daily dietary goals for the intervention group were 5 servings of vegetables, 16 ounces of vegetable juice, 3 servings of fruit, 30 grams of fiber, and 15% to 20% of energy from fat. Theory-based telephone counseling¹³ supplemented with 12 group cooking classes and monthly newsletters was used to deliver the intervention in 3 steps. In step 1, which included 3–8 counseling calls over 4–6 weeks, participants set short-term goals to build self-efficacy, and counselors monitored participants' dietary behaviors. In step 2, which included 8 counseling calls over 5 months, learned to navigate barriers to and monitor their progress towards dietary goals, and counselors guided participants toward making structural changes

(e.g., removing unhealthy foods from the home) and modifying recipes. In step 3, participants learned to habituate behaviors by evaluating their goals and maintaining their self-efficacy. The daily dietary goals for the comparison group consisted of 5 servings of vegetables and fruits, 20 grams of fiber, and 30% of energy from fat.¹⁴ In addition, participants in the comparison condition received 4 optional group cooking classes and dietary newsletters every other month.

Data Collection

Trained dietary assessors collected 24-hour recall data at baseline, the end of year 1, and the end of year 4. The 24-hour recalls consisted of 4 randomly selected recalls over a 3-week period for each participant. To increase the accuracy of the recalls, registered dietitians trained study participants to estimate food portion sizes. Recall data on fruits and vegetables were validated with plasma biomarkers.¹⁵ Dietary intake was estimated using the Nutritional Data System (Minneapolis, MN). In the current study, we used recall data to calculate fiber intake, servings of fruits and vegetables, and percentage of energy from fat.

Study Outcomes

The primary endpoints of the WHEL Study were breast cancer recurrence, new primary breast cancer, and death from any cause. In situ ductal or lobular carcinomas were not considered breast cancer recurrence or new primary breast cancer but were ascertained and recorded. The time to breast cancer event was defined as the time from randomization to the development of a recurrence or new primary breast cancer. Participant follow-up was censored at the time of death (if not from breast cancer), last documented staff contact date, or study completion (June 1, 2006). The endpoint was defined as death from any cause or censored at last follow-up. Each clinical site confirmed outcome events from medical records or death certificates, and an independent oncologist further confirmed each event.

Statistical Analyses

Descriptive statistics of medical and lifestyle factors were calculated for WHEL participants in each racial group. We used 1-way analysis of variance and the chi-squared test of independence to determine whether randomization achieved balance for demographic characteristics. We also used 1-way analysis of variance to determine whether dietary outcomes (i.e., fiber intake, servings of fruits and vegetables, and percentage of energy from fat) differed between racial groups at baseline. Next, we used linear mixed-effects models to examine within-group changes in dietary intake, time-by-group interactions, and time-by-group-by-race/ethnicity interactions. The fixed effects explored in these analyses consisted of time, group, and race/ethnicity, and all combinations of the three with participants nested within study conditions were treated as random effects.

In our final series of analyses, we used adjusted Cox proportional hazards models to determine whether there were racial differences in second breast cancer events and overall survival. Similarly, we used Cox models to examine the effects of the intervention on second breast cancer events and overall survival by racial group. All data were analyzed using SAS Enterprise Guide version 4.2 (SAS Institute Inc., Cary NC), and significance was determined at $P < 0.05$ with a 2-sided test.

RESULTS

Baseline Characteristics

We identified 3013 (98%) patients in the WHEL Study who had self-reported their race/ethnicity as Asian American, African American, Hispanic, or white. Patients' descriptive characteristics are reported in Table 1. Racial groups did not differ with regard to years since

diagnosis, disease stage at diagnosis, surgery type (mastectomy or lumpectomy), or radiation treatment (all $P > 0.05$). However, African American and Hispanic participants were younger, had higher body mass index (BMI), and were more likely to be premenopausal at study entry than Asian Americans and whites were (all $P < 0.05$). African Americans were less likely to report having undergone adjuvant anti-estrogen therapy, while Asian Americans were more likely to report having undergone anti-estrogen therapy ($P < 0.05$). Fewer whites than women of other races received chemotherapy.

The intervention and comparison groups did not differ with regard to years since diagnosis, disease stage at diagnosis, mastectomy, and adjuvant chemotherapy (all $P > 0.05$). Among Asian Americans, mean BMI was higher in the intervention group (25.6 kg/m^2) than in the comparison group (23.9 kg/m^2 , $P < 0.05$). Among African Americans, mean BMI was higher in the comparison group (32.4 kg/m^2) than in the intervention group (29.5 kg/m^2 , $P < 0.05$). Among Hispanics, participants in the intervention group were younger at diagnosis (46.6 years vs. 50.2 years), younger at study entry (48.9 years vs. 52.5 years), less likely to have undergone radiation treatment (54% vs. 72%), and more likely to be premenopausal (21% vs. 9%) (all $P < 0.05$). Among whites, intervention participants were more likely to have undergone adjuvant anti-estrogen therapy (71% vs. 66%, $P < 0.05$). Other factors, including tumor characteristics (i.e., grade, nodal status, and hormone-receptor status) and breast-sparing surgery were not different among races or between intervention and comparison groups (data not shown; all $P > 0.05$).

Dietary intake at baseline

Table 2 contains information about dietary patterns at baseline and changes in dietary patterns between baseline and the end of year 4. At baseline, African American and Hispanic participants received a significantly higher percentage of total energy from fat and consumed fewer daily servings of fruits and vegetables than Asian American and white participants (all $P < 0.01$). In addition, African American survivors consumed significantly less fiber than Asian American, Hispanic, and white survivors ($P < 0.01$), whereas Hispanic survivors consumed significantly less fiber than white survivors ($P < 0.05$) but not less fiber than African American or Asian American participants (Table 2).

Dietary Pattern over 4 Years

The intervention group as a whole exhibited significant improvements in fiber intake, servings of fruits and vegetables, and the percentage of energy from fat from baseline to the end of year 1 (all $P < 0.01$). Participants in the comparison group did not significantly change their diet, except for minimal improvements in servings of fruits and vegetables among white participants (both $P < 0.05$). For all ethnic groups, differences in dietary changes between the intervention and comparison arms translated into significant time-by-group interactions for fiber intake and servings of fruits and vegetables (all $P < 0.05$). In addition, significant time-by-group interactions were observed for the percentage of energy from fat for Asian American, Hispanic, and white participants (all $P < 0.01$), but not for African American participants ($P = 0.184$). Despite these differences between racial groups, none of the group-by-time-by-race/ethnicity interactions for the change between baseline and the end of year 1 were significant.

Survivors in the intervention group, regardless of race/ethnicity, exhibited modest regression to the mean from the end of year 1 to the end of year 4 but significant improvement in servings of fruits and vegetables from baseline to the end of year 4 (all $P < 0.05$). In addition, Asian American, Hispanic, and white participants had significant improvement in fiber intake from baseline to the end of year 4 (all $P < 0.05$); however, only white participants had significant improvement in the percentage of energy from fat ($P < 0.001$).

Significant time-by-group interactions for fiber intake and servings of fruits were observed in all racial groups in the intervention arm, whereas only Asian American, Hispanic, and white participants exhibited significant time-by-group interactions for servings of vegetables and percentage of calories from fat from baseline to the end of year 4 (all $P < 0.05$). The group-by-time-by-ethnicity interaction from baseline to the end of year 4 was significant ($P < 0.01$) only for servings of vegetables. These data suggested that the amount of change from baseline to the end of year 4 between the intervention and comparison groups was greater for white and Asian American participants than for African American and Hispanic participants ($P < 0.01$).

Recurrence and Mortality

Hazard ratios (HRs) and 95% confidence intervals (CIs) for breast cancer recurrence and overall survival rates are reported in Table 3. Breast cancer recurrence rates over a median follow-up of 7.3 years were similar among white (16.7%), African American, (18.6%), and Hispanic survivors (17.6%). However, Asian survivors had a significantly lower breast cancer recurrence rate than white survivors (9.4% event rate; adjusted HR = 0.50; 95% CI = 0.26, 0.97; $P = 0.04$). Mortality rates did not differ significantly among ethnicities.

The intervention effects are reported in Table 4. Overall, the WHEL Study intervention did not significantly impact breast cancer recurrence or overall survival rates for any racial group (Table 4), even after adjustment for age, radiation therapy, anti-estrogen therapy, and/or BMI.

DISCUSSION

In the present study, we found that regardless of race, participants randomized to the WHEL Study intervention group consumed significantly less dietary fat and significantly more fiber, fruits, and vegetables than participants randomized to the comparison group at the end of year 1. Participants in the intervention group also maintained improvements in fruit and vegetable consumption through the end of year 4. Although the dietary patterns improved significantly for all racial groups randomized to the intervention, none of the ethnic groups experienced reductions in breast cancer recurrence rates or improvements in overall survival. This secondary analysis of the WHEL Study confirmed the findings of previous analyses regarding dietary change achieved in the WHEL Study¹² and provides insight with respect to the effectiveness of a dietary intervention for minority cancer survivors.

Our secondary analysis of data from the WHEL Study, which was one of the first randomized trials to report on the dietary habits of minority cancer survivors, revealed that many breast cancer survivors do not meet the American Cancer Society's dietary guidelines.⁵ In addition, we observed that the dietary habits of African American and Hispanic survivors at baseline were worse than those reported by whites and Asian Americans. The racial differences in dietary intake among minorities at baseline may be due to social and cultural barriers such as differential body-image ideals (e.g., big is beautiful) and cultural food attitudes.¹⁶ Overcoming these cultural impediments may require developing new support networks that encourage and/or support positive health behaviors.¹⁷ In a recent study among African American breast cancer survivors,¹⁸ an intervention designed to build support by incorporating family and friends resulted in significant weight loss, dietary fat reduction, and increased fiber consumption. Therefore, interventions designed for minority survivors may be improved by incorporating the social network of the survivor.

The WHEL Study intervention was associated with substantial improvements in dietary intake among all survivors, regardless of race. The increases in fruit and vegetable intake exceeded those reported in previous intervention studies,^{19–23} and these improvements were

maintained at the 4-year follow-up. However, African American participants did not maintain improvements in fiber intake at the 4-year follow-up, and no racial group maintained meaningful improvements in dietary fat intake. Why survivors were unable to maintain improvements in dietary fat and fiber intake is unclear, therefore, alternative strategies, such as tailoring the dietary intervention to individual survivors' needs, are needed to maintain improvements in these behaviors as survivors move further from the intensive phases of the intervention.²⁴ Such strategies may be particularly beneficial for African American and Hispanic participants, because the magnitude of change in diet among these participants was not as great as that observed among Asian and white participants.

African American and Hispanic survivors did not differ from white survivors in the number of second breast cancer events or overall survival despite baseline differences in dietary intake. This result differs from population-based statistics,^{6, 7} which suggest that African American and Hispanic women have higher recurrence and mortality rates than white women. In fact, Asian Americans experienced lower recurrence rates than whites. Lower weight among Asian American women could have contributed to these differences, and if so, would confirm the results of previous studies suggesting that weight status may be an immediate causal factor in poor prognostic outcomes.^{25, 26} Therefore, regardless of race, women should consider adhering to the American Cancer Society's guidelines⁵ for maintaining a healthy weight in an effort to reduce the odds of poor breast cancer-related outcomes.

Despite the success of the telephone counseling,^{27–30} the WHEL Study intervention did not improve breast cancer recurrence or overall survival rates among minority breast cancer survivors. However, we know from healthy populations that a dietary pattern low in fat and high in fruits, vegetables, and fiber may reduce the risk of most chronic diseases.^{31, 32} Therefore, it is possible that survivors participating in the WHEL Study intervention may experience improvements in outcomes that extend beyond the study's completion date and that may be explored in future analyses of these data.

The results among our minority subgroups are similar to those reported in the primary analysis¹² but differ from those of interim analyses from the Women's Intervention Nutrition Study,³³ which found that a significant reduction in dietary fat was associated with 24% improvements in recurrence rates. The WHEL Study intervention may be beneficial for certain subgroups, as implied by the results observed among women who did not report hot flashes at baseline.^{27, 34, 35} However, more research and larger minority samples than available in the WHEL Study are needed to determine whether subgroup benefits are generalizable to minority breast cancer survivors.

The current study was not without potential limitations. For example, most of the patients in the current study had a high level of education and already had dietary patterns that closely reflected the guidelines recommended by the American Cancer Society. Therefore, the results of the current study may not be generalizable to all populations of breast cancer survivors. In addition, our multiple 24-hour dietary recalls for each participant were self-reported; thus, the study had the potential for inaccurate recall and reporting biases. Furthermore, this study was not powered to examine race/ethnicity differences and survivors were only followed for a median of 7.3 years. This length of time may not be long enough to see the effects of a dietary intervention in relatively healthy sample of breast cancer survivors. Despite its potential limitations, the current study had a number of notable strengths, including a randomized design, which eliminated selection bias; 24-hour recall data on fruit and vegetable intake, which was significantly correlated with plasma carotenoid levels;^{36, 37} inclusion of premenopausal and postmenopausal women; and inclusion of women with aggressive tumors.³⁸

In conclusion, this secondary analysis demonstrated that the WHEL Study intervention was effective in changing dietary intake in all survivors, regardless of race; however, African American women were less likely to maintain these improvements over time. In addition, lower breast cancer recurrence rates observed among Asian women may suggest that we should look to this group as a model for healthy behaviors. That said, more research is needed to identify lifestyle factors that reduce rates of breast cancer recurrence and mortality and improve health-related quality of life. Furthermore, there is a need for more research powered to examine racial differences in the context of long-term lifestyle interventions.

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Figure 1.
Consort Chart of the Women's Healthy Eating and Living Study.

Table 1
Baseline descriptive characteristics for Women's Healthy Eating and Living Study participants by race.

Variable	Asian American n = 96	African American n = 118	Hispanic n = 165	white n = 2634	P value [†]
Median age at randomization, (25%, 75%)	52 (47, 58)	49 (43, 54)	50 (44, 57)	52 (47, 59)	<0.001
Median time from diagnosis, (25%, 75%)	2 (1, 3)	2 (1, 3)	2 (1, 2)	2 (1, 3)	0.216
Median age at diagnosis, (25%, 75%)	50 (45, 56)	47 (42, 52)	48 (42, 55)	51 (45, 57)	<0.001
Median body mass index, (25%, 75%)	24.4 (22, 28)	29.3 (26, 34)	26.9 (24, 31)	25.7 (23, 30)	<0.001
Stage of diagnosis, n (%)					0.308
I	41 (43)	38 (32)	51 (31)	1034 (39)	
IIA	28 (29)	44 (37)	71 (43)	861 (33)	
IIB	12 (13)	18 (15)	15 (9)	322 (12)	
IIIA	12 (13)	15 (13)	20 (12)	319 (12)	
IIIC	3 (3)	3 (3)	8 (5)	98 (4)	
Treatment, n (%)					
Mastectomy/Lumpectomy	55 (57)	59 (50)	87 (53)	1366 (52)	0.725
Radiation	56 (59)	79 (67)	103 (62)	1622 (62)	0.639
Adjuvant chemotherapy	73 (76)	91 (77)	129 (78)	1814 (69)	0.010
Anti-estrogen therapy	75 (78)	68 (56)	108 (65)	1807 (69)	0.011
% Premenopausal	9 (9)	22 (19)	25 (15)	286 (11)	0.020

Note: All data are no. of patients (%) unless otherwise indicated.

[†] Compares descriptive characteristics between racial groups. Continuous P-values are base on nonparametric Kruskal Wallis test, whereas categorical P-values are based on chi-square test for independence.

Table 2
Dietary factors for selected change at baseline and over time by study condition and racial group

Ethnic group and P value	Calories from fat, %			Fiber, g/day			Fruit servings/day			Vegetable servings/day		
	Mean at baseline (SD)	Mean change at 1 year	Mean change at 4 years	Mean at baseline (SD)	Mean change at 1 year	Mean change at 4 years	Mean at baseline (SD)	Mean change at 1 year	Mean change at 4 years	Mean at baseline (SD)	Mean change at 1 year	Mean change at 4 years
Race P value	< 0.001			< 0.001			< 0.001			< 0.001		
Asian American												
Intervention group	27.2 (7.2)	-4.2 [†]	-0.7	19.8 (7.0)	8.0 [‡]	6.4 [†]	2.6 (1.6)	1.0 [†]	0.8 [*]	3.0 (1.8)	2.1 [‡]	2.0 [‡]
Comparison group	27.4 (6.8)	0.2	2.8 [*]	20.1 (6.8)	-1.0	-1.6	2.7 (1.8)	-0.1	-0.2	3.4 (2.1)	-0.3	-0.6
Time-group P value		0.005	0.038		< 0.001	< 0.001		0.017	0.024		< 0.001	< 0.001
African American												
Intervention group	29.6 (6.1)	-4.0 [†]	-0.1	16.9 (6.8)	5.5 [‡]	2.6	1.8 (1.5)	1.1 [†]	0.8 [*]	2.4 (1.2)	1.2 [‡]	0.7 [*]
Comparison group	32.7 (6.0)	-1.5	0.4	15.9 (6.7)	-1.0	-0.8	1.7 (1.7)	-0.1	-0.5	2.1 (1.4)	-0.2	0.4
Time-group P value		0.184	0.779		< 0.001	< 0.024		0.006	0.005		< 0.001	0.472
Hispanic												
Intervention group	30.4 (6.9)	-5.7 [‡]	-1.4	19.7 (6.5)	5.0 [‡]	2.7 [*]	1.9 (1.4)	1.1 [‡]	0.8 [†]	2.7 (1.6)	1.4 [‡]	0.8 [‡]
Comparison group	30.2 (6.8)	-0.7	1.4	19.6 (7.7)	-0.1	-3.0 [†]	2.0 (1.5)	0.3	-0.0	2.4 (1.6)	0.0	-0.4
Time-group P value		< 0.001	0.020		< 0.001	< 0.001		0.010	0.019		< 0.001	< 0.001
white												
Intervention group	28.5 (7.2)	-5.8 [‡]	-1.2 [‡]	21.4 (8.4)	7.8 [‡]	3.7 [‡]	2.5 (1.8)	1.0 [‡]	0.5 [‡]	2.9 (1.7)	1.7 [‡]	1.3 [‡]
Comparison group	28.4 (7.0)	-0.2	3.0 [‡]	21.5 (8.1)	-0.2	-2.1 [‡]	2.4 (1.7)	0.1 [*]	-0.3 [‡]	2.9 (1.7)	0.1 [*]	0.0
Time-group P value		< 0.001	< 0.001		< 0.001	< 0.001		< 0.001	< 0.001		< 0.001	< 0.001
Time-group-race P value												
		0.134	0.169		0.164	0.442		0.806	0.670		0.169	0.002

Note: Estimates of change are expressed for within-group differences from baseline to the indicated time point. Race P values represent baseline differences between racial groups among dietary components. Time-group P values represent time-by-group interactions comparing the degree of change from baseline to the indicated time point between study conditions. Time-group-race P values represent time-by-group-by-race interactions comparing the degree of change from baseline to the indicated time points among racial groups and between study conditions.

SD = standard deviation.

* Significance at $P < .05$.

[†] Significance at $P < .01$.
[‡] Significance at $P < .001$.

Table 3

Cox proportional hazard ratios for recurrence and mortality

Race	No. of participants	Participants whose disease recurred, %	Breast cancer recurrence HR (95% CI)	P value	Participant deaths, %	Mortality, HR (95% CI)	P value
Asian	96	9.4	0.50 (0.26 – 0.97)	0.040	8.3	0.86 (0.43 – 1.75)	0.686
African-American	118	18.6	1.08 (0.70 – 1.66)	0.733	13.6	1.28 (0.77 – 2.14)	0.343
Hispanic	165	17.6	1.00 (0.69 – 1.46)	0.992	10.9	0.98 (0.61 – 1.59)	0.948
white	2634	16.7	– 1 –	Referent	9.9	– 1 –	Referent

Note: All models were adjusted for tumor stage, grade, and body mass index.

HR = hazard ratio; CI = confidence interval.

Survivors were followed for a mean of 7.3 years.

Cox proportional hazard ratios modeling the Women's Healthy Eating and Living Study intervention effects on recurrence free and overall survival by ethnicity

Table 4

Race	No. of participants in the intervention group whose disease recurred	No. of participants in the comparison group whose disease recurred	Breast cancer events, HR (95% CI)	P value	No. of deaths in the intervention group	No. of deaths in the comparison group	Mortality, HR (95% CI)	P value
Asian *	6/46	3/50	2.09 (0.52 – 8.49)	0.300	4/46	4/50	0.85 (0.20 – 3.50)	0.819
African-American *	14/61	8/57	1.61 (0.67 – 3.87)	0.288	10/61	6/57	1.45 (0.52 – 4.03)	0.477
Hispanic [†]	13/87	16/78	0.67 (0.31 – 1.43)	0.362	8/87	10/78	0.70 (0.26 – 1.87)	0.479
white [‡]	216/1306	223/1328	0.98 (0.82 – 1.19)	0.864	127/1306	133/1328	0.98 (0.77 – 1.30)	0.868

Note: Adjustments were made based on baseline differences between intervention and comparison conditions.

HR = hazard ratio; CI = confidence interval.

Survivors were followed for a mean of 7.3 years

* Models were adjusted for baseline body mass index.

[†] Models were adjusted for age at study entry, age at diagnosis, radiation treatment and menopausal status.

[‡] Models were adjusted for anti-estrogen use.