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***¡Cocinar Para Su Salud!*: Randomized controlled trial of a culturally-based dietary intervention among Hispanic breast cancer survivors**

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Abstract

BACKGROUND—There is a need for culturally-relevant nutrition programs targeted to underserved cancer survivors.

OBJECTIVE—To examine the effect of a culturally-based approach to dietary change on increasing fruit/vegetable intake and decreasing fat intake among Hispanic breast cancer (BC) survivors.

DESIGN—Participants were randomized to intervention (IG) and control (CG) groups. Diet recalls, detailed interviews, fasting blood, and anthropometric measures were collected at baseline, 3-, 6- and 12-months.

PARTICIPANTS/SETTING—Hispanic women (n=70) with stage 0-III BC who completed adjuvant treatment and lived in New York City were randomized between April 2011 and March 2012.

INTERVENTION—The IG (n=34) participated in *¡Cocinar Para Su Salud! (¡CPSS!)*, a culturally-based 9-session (24-hours over 12 weeks) intervention including nutrition education, cooking classes and food shopping field trips. The CG (n=36) received written dietary recommendations for BC survivors.

MAIN OUTCOME MEASURES—Change at 6 months in daily fruit/vegetable servings and % calories from total fat.

STATISTICAL ANALYSES—Linear regression models adjusted for stratification factors and estimated marginal means were used to compare changes in diet from baseline to 3- and 6-months.

RESULTS—Baseline characteristics: mean age 56.6 years (SD 9.7), mean time since diagnosis 3.4 years (SD 2.7), mean BMI 30.9 kg/m² (SD 6.0), 62.9% with annual household income \$15,000, average daily servings of all fruits/vegetables 5.3 (targeted fruits/vegetables 3.7 servings excluding legumes/juices/starchy vegetables/fried foods) and 27.7% of daily calories from fat. Over 60% in the IG attended 7/9 classes with overall study retention of 87% retention at 6 months. At month 6, the IG compared to CG reported an increase in mean servings of fruits/vegetables from baseline (all fruits/vegetables: +2.0 vs. -0.1, P=0.005; targeted fruits/vegetables: +2.7 vs. +0.5, P=0.002) and a non-significant decrease in % calories from fat (-7.5% vs. -4.4%, P=0.23) and weight (-2.5kg vs. +3.8kg, P=0.22).

CONCLUSIONS—*¡CPSS!* was effective at increasing short-term fruit/vegetable intake in a diverse population of Hispanic BC survivors.

Keywords

clinical trial; breast cancer; nutrition education; dietary intervention; minority

INTRODUCTION

Current guidelines for cancer survivors recommend a diet high in fruits and vegetables, and low in energy dense foods, such as foods high in fats and sugars, in order to improve clinical outcomes.^{1,2} However, there are limited resources available to cancer survivors to help them achieve these behavioral recommendations and few cancer survivors meet the recommendations. The American Cancer Society (ACS) reports that only 18% of breast cancer survivors eat the recommended 5 servings of fruits and vegetables per day.³ Individuals of lower socioeconomic status are even less likely to adhere to the guidelines.⁴

It is well established that simply providing dietary recommendations to any patient population will not achieve sustained dietary change³ and there is a paucity of data on how to effectively motivate breast cancer survivors to adhere to dietary recommendations, especially in minority and low-income populations. To date, the majority of dietary interventions among cancer survivors have been targeted to the mainstream non-Hispanic white US population.^{5,6} There is a need for culturally relevant and appropriate nutrition programs targeted to underserved populations of cancer survivors.

Since 2011, Hispanics have become the largest minority population in the United States, representing a diverse constellation of nationalities, ethnicities and cultural norms.⁷ Of the current estimated 12 million cancer survivors, an estimated 5% are Hispanic.⁸ Conducting intervention studies among Hispanic populations is particularly important because these groups may be at greater risk of breast cancer recurrence compared to non-Hispanic whites due to high rates of obesity⁹, lower rates of physical activity¹⁰, and poorer access to quality health care.¹¹ Although Hispanic women have a lower incidence rate of breast cancer than non-Hispanic white women, Hispanic women are 20% more likely to die of breast cancer than non-Hispanic white women who are diagnosed at a similar age and stage.¹² Additionally, Hispanic sub-groups may face specific barriers to achieving dietary change, including cultural norms, health literacy, language, and food access.

Study investigators partnered with the New York City-based nonprofit organization, Cook For Your Life (www.cookforyourlife.org), to develop and conduct a 3-month culturally-based dietary intervention, *¡Cocinar Para Su Salud! (Cook For Your Health!)*, among Hispanic breast cancer survivors. Cook For Your Life had previously implemented single session community classes in multiple New York City locations, without formal evaluation. Study investigators worked with Cook For Your Life community educators, including registered dietitians, other nutrition educators, chefs and community organizers, to develop a longer curriculum with specific goals and a formal assessment of behavior change outcomes. The goal of the intervention was to test whether a focused approach to dietary behavioral change could be effective in assisting women to achieve and maintain the dietary guidelines put forth by the American Institute for Cancer Research (AICR) and ACS.^{1,2} As such, the intervention did not focus on changing other lifestyle behaviors included in the guidelines, including body size and physical activity. This manuscript reports on the planned primary outcomes examining the effects of a culturally-based approach to dietary change on increasing fruit/vegetable intake and decreasing fat intake among Hispanic breast cancer

survivors over 6 months. Long-term 12 month data will be presented in a future manuscript and will explore predictors of dietary change.

METHODS

Study design and participant recruitment

This study was a randomized controlled trial designed to examine the effects of a 9-session (24-hours over 12 weeks), culturally based dietary intervention vs. standard written materials on change in fruit and vegetable and total fat intake among Hispanic breast cancer survivors. Spanish-speaking women with a history of stage 0-III breast cancer and who were at least 3 months post-treatment (surgery, radiation or chemotherapy; current hormonal therapy allowed) with no evidence of metastatic disease were recruited from the Columbia University Medical Center (CUMC) Breast Oncology Clinic between January 2011 and March 2012. Women were screened for the following eligibility criteria: age 21 years; Hispanic descent and fluent in Spanish; no uncontrolled diabetes mellitus, defined as hemoglobin A1C >7%; no uncontrolled comorbidities (e.g., hypertension); currently a non-smoker (given the low likelihood of current smokers to engage in healthy lifestyle behaviors); average intake of <5 servings of fruits and vegetables per day as assessed by the Block Fruit/Vegetable/Fiber Screener¹³; access to a functional home or cell phone; and not currently active in a dietary change program. A detailed screening interview assessed previous medical history, reproductive history, family history, demographic information, physical activity, use of concomitant medications, and acculturation. Acculturation was assessed using the Short Acculturation Scale for Hispanics (SASH), which assesses acculturation based on language use, media, and ethnic-social relations.^{14,15} The study was approved by the CUMC and Columbia University Teachers College institutional review boards (ClinicalTrials.gov NCT01414062). All participants provided written informed consent.

Baseline data collection

Once participants completed the screening questionnaire, eligible participants were contacted and scheduled for a baseline clinic visit to occur within two weeks prior to the dietary intervention program start date. This scheduling was necessary to allow women to enroll in the study in intervention group cohorts. Clinic visits took place at the Herbert Irving Center for Clinical and Translational Research at CUMC. During clinic visits, the following procedures were conducted: assessment of anthropometric measures by trained study staff using a standardized protocol [height was measured using a calibrated Genentech Accustat stadiometer (San Francisco, CA), weight was measured using a calibrated SR Instruments SRscale (Towanda, NY), waist and hip circumferences were measured using a Gulick II tape measure (Country Technology, Gays Mills, WI); fasting blood collection for planned future biomarker analysis including, carotenoids and tocopherols as markers of dietary intake, metabolic markers (e.g., insulin, glucose, insulin-like growth factor-I), markers of inflammation (e.g., C-reactive protein, IL-6), and DNA methylation; and completion of a detailed interviewer administered questionnaire, including questions related to stages of change, frequency of diet-related behaviors, social support, anxiety and depression, health behaviors and psychosocial constructs. Health literacy and ability to read

food labels was also assessed at this time using the Newest Vital Sign.¹⁶ Baseline dietary intake was assessed by a registered dietitian using three 24-hour recall assessments (2 weekdays, 1 weekend day) using the multiple pass approach¹⁷ and using the Nutrition Data System for Research (NDSR version 2011, (2011) developed by the Nutrition Coordinating Center (NCC), University of Minnesota, Minneapolis, MN) (one in-person during the baseline clinic visit, two by phone). The registered dietitian who conducted the dietary recalls was not the registered dietitian who was the intervention group facilitator. Baseline physical activity was assessed using the Block Physical Activity Screener.¹⁸

Randomization

A randomization sequence was generated by the study biostatistician and sealed in envelopes marked with a numerical code. Randomization used a permuted block design and women were stratified at enrollment based on 1) menopausal status and 2) current use of anti-hormonal breast cancer treatment. Participants and research team were unaware of group assignment prior to randomization. Upon completion of baseline data collection, eligible participants were randomly allocated to the intervention group: the 9-session (24-hours over 12 weeks) *¡Cocinar Para Su Salud!* program, or the control group: standard of care written dietary recommendations for cancer survivors¹⁹ presented by a member of the research team. Women were randomized into the study in cohorts to allow women to begin the classes in groups of 4–12 participants.

Intervention

¡Cocinar Para Su Salud! was designed as a 9-session (24 hours over 12 weeks) nutrition intervention program using a culturally-tailored curriculum developed exclusively for this study that primarily focused on helping cancer survivors achieve and maintain the nutrition-related guidelines set forth by the ACS and AICR.^{1,2} The goal of the intervention was to provide women with knowledge and skills that they could use to modify their dietary behaviors during the course of the study, and then have the skillset necessary to maintain the changes in their lives going forward. The study's primary aim was to assess the effectiveness of the *¡Cocinar Para Su Salud!* curriculum on modifying dietary behaviors, therefore physical activity and body weight were not targeted by the intervention. Nine intervention sessions were conducted over a period of 12 weeks for a total of 24 hours. Sessions were scheduled on Saturday mornings and ranged from 1.5 to 3.5 hours in duration (Table 1). Classes were held in the teaching kitchen at Columbia University's Teachers College. The intervention was based upon classes developed by the New York City nonprofit organization, Cook For Your Life (www.cookforyourlife.org) and modified for the target population. An interdisciplinary team of clinical trialists, physicians, epidemiologists, nutritionists, registered dietitians and health educators used Contento's model for designing nutrition education curricula as the conceptual framework for developing and refining the intervention curriculum.²⁰ Target behaviors were identified based on the ACS and AICR dietary recommendations for cancer survivors.^{1,2} Targeted behaviors included eating more fruits and vegetables and decreasing fat intake through fewer and leaner meats, fewer and lower fat dairy products, and using less fat during cooking. The intervention emphasized the benefit of increasing all fruits and vegetables, and particularly emphasized increasing dark leafy greens and cruciferous vegetables; the intervention suggested that women not consider

fruit juices, potatoes, fried vegetables (e.g. plantains) and legumes as targeted fruit/vegetables. Social Cognitive Theory²¹ and the Stages of Change Construct of the Transtheoretical Model²² were selected as theoretical frameworks to identify mediators of behavioral change for each lesson. Neighborhood research and information interviews were used to identify specific behavioral objectives to address pre-identified mediators of change and facilitate movement across stages of change. Neighborhood assessments and informal interviews were conducted in order to tailor the curriculum to Hispanics. Recipes were developed based on traditional Latin American cuisine. Cultural values related to family and community were acknowledged and addressed throughout the sessions as potential facilitators and barriers to dietary change. All class materials and assessments were translated into Spanish. Focus groups were conducted to assess language level and content validity. Sessions were conducted entirely in Spanish and were facilitated by a bilingual, Hispanic registered dietitian and a bilingual, Hispanic chef. The 9 sessions included 4 nutrition education roundtables, 3 hands-on cooking classes, and 2 food shopping field trips.

Nutrition roundtables—Four 2-hour nutrition education classes were used to promote dietary change, provide information about the potential benefits of dietary change, and improve health literacy. The sessions were designed as interactive roundtables, with participants sitting in a semi-circle with the registered dietitian facing the class. Interactive presentations and discussions were framed to enhance participants' movement through the stages of change, focusing on the two mediators of change from the Transtheoretical Model -- pros and cons of change and self-efficacy -- and using behavior change strategies from Social Cognitive Theory. Early discussions focused on self-assessment of intake compared to dietary cancer prevention guidelines to increase concern and the perceived benefits of the targeted behaviors (or pros of change). Later sessions focused on the skills and strategies needed to increase self-efficacy to implement change to eat a healthy diet, and skills in solving problems involving food and family, meal budgeting and meal planning to maintain change for the long term. As the lessons progressed, the roundtables became a forum for participants to develop self-regulation skills through discussing changes they were able to achieve, troubleshooting barriers (e.g., familial resistance to dietary change), and facilitating further changes (Table 1).

Cooking classes—Three 3.5-hour hands-on cooking classes were an integral part of the skills-building aspect of the intervention. The main purpose of the cooking classes was to show women ways to adapt new cooking methods and patterns of eating to familiar foods, and to use traditional herbs and spices to facilitate the incorporation of unfamiliar foods into their diets, particularly leafy greens. Cooking classes were built sequentially and reflected the main themes touched upon in previous nutrition roundtables. Cooking techniques emphasized increasing fruit and vegetable consumption and reducing fat intake. Participants prepared and then shared the meal together and participated in a facilitated discussion of barriers to sustaining dietary change (Table 1).

Food shopping field trips—Two 1.5-hour food-shopping field trips were used to teach women how to shop for healthy foods in the neighborhoods in which they live. Field trips included visiting a local large supermarket and a local greenmarket and each ended with a 1-

hour discussion to review what was learned and to discuss how to troubleshoot barriers to change (Table 1).

Control Group

The control group received a 22-page Spanish-language booklet on healthy eating for breast cancer survivors.¹⁹ Participants in the intervention arm also received a copy of this booklet. The materials review similar themes to those covered in the intervention class (i.e., eating more fruits and vegetables and decreasing dietary fat) in addition to addressing other dietary recommendations for breast cancer survivors. However, the booklet only contained the knowledge and skills that would be useful for those already in the maintenance stage, and does not move individuals from contemplation to action as is emphasized in the *¡Cocinar Para Su Salud!* curriculum. At the completion of the study, participants in the control group were provided information about Cook For Your Life as a community-based organization that provides nutrition information to cancer survivors.

Follow-up data collection

Participants were scheduled for clinic visits at 6- and 12 months after baseline data collection. Fasting blood, anthropometric measures, three 24-hour dietary recalls and interviewer-administered detailed questionnaires were completed at each time point. Three 24-hour dietary recalls and interviewer-administered questionnaires were completed via telephone at 3 months. Additionally, all participants were contacted by the study coordinator (a registered dietitian) via telephone every month to briefly assess diet behaviors and to promote retention.

STATISTICAL METHODS

Our *a priori* hypothesis to test was whether *¡Cocinar Para Su Salud!* would increase daily servings of fruits and vegetables and decrease fat as a percentage of daily calories in the intervention group compared to the control group. In order to have sufficient power to determine the effect of the intervention, 30 patients per treatment group were needed for an overall sample size of 60. Power calculations used two-sided statistical tests for the change in the primary outcomes (change in intake of servings of fruit/vegetables and percent calories from fat). A dropout rate of 15% at 6 months was anticipated, therefore the targeted recruitment goal was 70 women. Unadjusted comparisons between groups on baseline demographics, acculturation, and clinical measures were conducted using two-sample *t* tests and Pearson χ^2 analysis. Statistical tests used $\alpha = 0.05$ and two-sided *p*-values. Comparisons between groups in baseline dietary outcomes and anthropometric measures and change in these measures from baseline to 3 and 6 months were assessed using estimated marginal means derived from linear regression models. The models used a covariate-adjusted analysis adjusting for randomization stratification factors, including menopausal status (premenopausal vs. postmenopausal) and use of anti-hormonal breast cancer treatment (yes vs. no) at baseline.²³ All other covariates were well balanced and therefore in order to avoid over adjustment other covariates were not included in the regression models. All analyses were performed using Stata 12.1 (release date January 2012; College Station, TX).

RESULTS

Recruitment, baseline characteristics, enrollment and retention

Between April 7, 2011 and March 30, 2012, 70 women were randomized into the intervention (n=34) and control (n=36) arms. The median number of days between screening and randomization was 43 days. A CONSORT diagram is illustrated in Figure 1. At study enrollment, participants' scored an average of 11.6 (SD 4.2) on the Block Fruit/Vegetable/Fiber Screener, translating to fewer than 4 servings of fruits/vegetables per day (data not shown). At baseline, there were no statistically significant differences between the intervention and control groups for all but one demographic/clinical characteristic (Table 2). The control group had lower household incomes ($P=0.05$). At baseline, the combined average age of participants was 56.6 years (SD 9.7). All women self-identified as Hispanic. The majority (77.1%) of women were Dominican, followed by Puerto Ricans (7.1%) and Ecuadorians (7.1%). On average, women reported low levels of acculturation as assessed by the SASH acculturation index [mean (SD), 1.6 (0.6); range 1.0–3.6]. Sixty percent of women reported a high school education or less, 40% reported working full- or part-time, and 62.9% reported an annual household income of \$15,000. Over half (58.6%) of study participants reported current participation in a food stamps program. On a six-point scale, the total study population had a mean health literacy score of 1.5 (SD 1.8), suggesting a high likelihood (50% or more) of limited health literacy. Approximately one quarter of participants had been diagnosed with ductal carcinoma in situ and one third had stage I tumors. Average time since diagnosis was 3.4 years (range: 0.3–15.6 years). Mean body mass index (BMI, data not shown) of study participants was 30.9 kg/m^2 (SD 6.0). On average, women self-reported participating in 519 (SD 584) minutes of moderate physical activity per week through their daily activities, and very little vigorous physical activity [mean 2.5 (SD 14.1) minutes per week]. At month 3, 67 women (96%) remained in the study (n=31, intervention; n=36, control), and at month 6, 61 women (87%) were retained (n=30, intervention; n=31, control).

Baseline dietary intake

At baseline, women reported an average total caloric intake of 1,593 kcal per day, 27.7% of which was calories from fat. Based on three 24-hour recalls at baseline, average intake of all fruits and vegetables was 4.7 (2.2 fruits; 2.5 vegetables) and 5.8 (2.7 fruits; 3.2 vegetables) servings per day for the intervention and control groups, respectively. When baseline fruit and vegetable intake was restricted to those targeted by the intervention, mean total intake of fruit and vegetables was 3.4 (1.4 fruits; 2.0 vegetables) and 3.9 (1.8 fruits; 2.1 vegetables) servings per day for the intervention and control group ($P=0.34$), respectively (Table 3).

Intervention attendance and change in dietary intake of fruits/vegetables

Over one-third (38%) of participants in the intervention arm attended all 9 sessions, 26% attended 7–8 sessions, 18% attended 1–6 sessions, and 18% did not attend any sessions. At month 3, the intervention arm compared to controls reported an increase in mean servings of fruit/vegetables per day (all fruits/vegetables: +1.1 vs. -0.3, $P=0.05$; targeted fruits/vegetables: +2.0 vs. 0.2, $P=0.004$) (Table 3). The increase in vegetable servings among the intervention group accounted for the majority of the difference between the intervention and

control groups at 3 months (all vegetables: +1.0 vs. -0.4, $P=0.004$; targeted vegetables: +1.2 vs. -0.2, $P=0.001$). Changes were maintained at month 6; the intervention group compared to controls reported an increase in mean servings of fruits/vegetables from baseline (all fruits/vegetables: +2.0 vs. -0.1, $P=0.005$; targeted fruits/vegetables: +2.7 vs. +0.5, $P=0.002$). Specifically, at 6 months intake of dark-green ($P<0.001$) and deep-yellow ($P=0.03$) vegetables increased (On-line Supplemental Table 1). As at month 3, almost all of the difference between the intervention and control groups at 6 months was accounted for by an increase in vegetable consumption among the intervention group (all vegetables: 1.8 vs. 0.2, $P=0.005$; targeted vegetables: 1.8 vs. 0.6, $P=0.02$).

Change in dietary intake of percent calories from fat

At month 3, the intervention arm compared to controls reported a decrease in percent calories from total fat (-7.1% vs. -1.6%, $P=0.01$) and saturated fat (-3.8% vs. -0.3%, $P<0.001$) (Table 3). At 6 months, the change in the intervention arm was maintained for both total fat and saturated fat, but the control arm also showed a decrease in both and the difference was no longer statistically significant (total fat: -7.5% vs. -4.4%, $P=0.23$; saturated fat: -3.1% vs. -1.5%, $P=0.14$). Though the intervention did not focus on decreasing caloric intake, the intervention group reported an average >500 kcal/day reduction at both 3 and 6 months, compared to a <100 kcal/day reduction in the control group.

Change based on intervention attendance

In order to examine whether session attendance was associated with dietary change, participants in the intervention were divided into two groups based on the median attendance of the 9 sessions: those who attended ≥ 7 sessions vs. those who attended <7 sessions. The only difference between the two groups was that at both 3 and 6 months, those with higher attendance reported greater change in intake of dark-green vegetables compared to baseline (3 months: 0.7 vs. 0.2, $P=0.04$; 6 months: 0.8 vs. 0.4, $P=0.058$) (data not shown).

Change in anthropometric measures

At month 6 there was a non-significant trend in the difference in percent weight change between the two groups (Table 4); women in the intervention arm lost an average of 2.5%, whereas women in the control arm gained an average 3.8 % ($P=0.22$). There a significant difference in waist circumference between the two groups at 6 months: women in the intervention group had an average decrease of 1.6 cm, while women in the control arm had an average increase of 1.7 cm ($P=0.05$).

DISCUSSION

The 3-month ¡Cocinar Para Su Salud! culturally-based dietary intervention successfully increased the combined intake of fruit and vegetables among a diverse group of urban Hispanic breast cancer survivors, the majority of whom were of low socioeconomic status, and the dietary changes persisted at six months. Future analyses will investigate specific factors related to dietary change. The intervention focused on helping women achieve and maintain the dietary composition guidelines set forth by the AICR and ACS.^{1,2} Women in

the intervention group ate more daily servings of fruits and vegetables than women in the control group, and most importantly, they ate more dark-green and deep-yellow vegetables. At 3 months, there was a decrease in the daily percent calories from fat among the intervention group compared to the control group, but this difference did not remain at 6 months, partially because the control group also changed their diet. The intervention was designed to increase fruit and vegetable consumption and decrease dietary total fat intake using a culturally-based, hands-on educational approach. The intervention used nutrition roundtables, food shopping field trips, and cooking classes to teach breast cancer survivors how to effectively adopt dietary recommendations for cancer survivors. According to current guidelines for cancer survivors, changes in these dietary behaviors have the long-term potential to reduce breast cancer mortality, as well as comorbid obesity and related conditions such as diabetes and cardiovascular disease.^{1,2}

Study results show that the hands-on skills and knowledge building approach to dietary change was effective in this patient population, who had low levels of health literacy and acculturation, and very limited access to financial resources (over half of study participants were in a food assistance program and had annual household incomes less than \$15,000 per year). In this population, barriers to healthy eating are likely heavily tied to cost of foods. The rationale for conducting local food shopping field trips was to provide women with knowledge and skills to be able to successfully purchase healthy foods in their neighborhoods. For example, women were provided with cost comparison sheets showing them where to purchase affordable produce and lower fat meats in their neighborhoods. It is important for dietary intervention studies among any population to factor in the sustainable cost of long-term adherence to dietary recommendations.

Although this intervention did not evaluate the relationship between dietary change and cancer-related outcomes, these findings are both noteworthy and encouraging given the lack of previous studies evaluating dietary behavior change among Hispanic breast cancer survivors and the relatively high cancer mortality among this population.^{12,24–26} There is currently conflicting evidence on whether changes in postdiagnosis dietary patterns affect breast cancer prognosis, and the two studies that have been conducted were among primarily non-Hispanic breast cancer survivors.^{27,28} The Women's Healthy Eating and Living (WHEL) study intervention achieved substantial dietary change (increase in fruits/vegetables, decrease in dietary fat) via telephone counseling, with 12 cooking classes and monthly newsletters for one year and did not find any association between diet and cancer-related outcomes. However, the WHEL population had a baseline intake of 6 servings of fruits/vegetables per day, which is substantially higher than the *¡Cocinar Para Su Salud!* population. In addition, the WHEL participants had an average intake of 28.6% kcal/fat, which was lower than the *¡Cocinar Para Su Salud!* population and less than 15% of the WHEL participants belonged to a minority group. The Women's Intervention Nutrition Study (WINS) achieved substantial reductions in dietary fat via bi-weekly, individual, in-person counseling sessions, and subsequent dietitian visits or calls every 3 months (if available, group meetings were also provided). WINS survival analyses did show an improvement in cancer-related outcomes related to the intervention. The baseline diet of the WINS participants consisted of 29.6% kcal/fat and only 4% of the WINS population was

Hispanic. There is a lack of culturally-based dietary interventions and studies examining behavioral change specifically among minority breast cancer survivors. The study reported here was unique in that it used a culturally-based hands on approach focused on meeting diet composition recommendations for cancer survivors among a minority population.

Excess body weight and low levels of physical activity are prevalent among Hispanics in the U.S.²⁹ There is evidence that obesity and overweight can increase the risk of breast cancer in women, including secondary cancers.² On average, participants in *¡Cocinar Para Su Salud!* were more likely to be obese compared to WHEL or WINS; WHEL participants had an average BMI of 27.2 kg/m² and 27% of the WINS population was obese.^{27,28} It is important to note that *¡Cocinar Para Su Salud!* specifically focused on targeted changes in diet composition and diet patterns, not caloric restriction. As is evidenced by study results, a modification in diet composition resulted in a decrease in calories and subsequent weight loss. Though the intervention did not target weight loss per se, the intervention did show a trend towards clinically meaningful weight loss. Studies have shown that even a 5% weight loss at 6-months might be beneficial in reducing hypertension, cardiovascular and diabetes risk factors.^{30–33} Future interventions can include weight loss and physical activity components to address obesity related risk factors among this population.

The trial had good retention at 6 months, but only 38% of participants attended all 9 sessions. It is possible that the low attendance was partially due to the delay between screening and the intervention and also because of the time constraints of a 9-session class. Sessions were scheduled to not fall on major holiday weekends, but some sessions did fall on days with poor weather conditions, which may have also decreased attendance. Prior studies have shown that minority populations are less likely to adhere to prevention interventions compared to female and male non-Hispanic whites.³⁴ Language, family support, work and time constraints have been reported as barriers to adherence in minority populations.^{35,36} By 2030, Hispanics will constitute 30% of the general population.⁷ Addressing adherence barriers is crucial in order to increase minority participation in effective behavioral interventions among high-risk populations. This study addressed specific barriers related to adherence in Hispanics such as family support, transportation and language and literacy barriers. The intervention was conducted entirely in Spanish and the intervention facilitated a group setting where women were able to brainstorm ideas on how to involve their families. In addition, all study-related assessments were conducted by Spanish-speaking staff and were interviewer-administered, addressing potential language and literacy barriers. Future interventions will need to better address potential barriers to participation related to time constraints and delays by possibly having shorter and/or fewer in-person classes, as well as possibly exploring methods for internet-based interventions.

To our knowledge, this is one of the few dietary interventions specifically targeting minority breast cancer survivors with low fruit and vegetable intake. A strength of this study is the use of a rigorous randomized, controlled study design to test the effects of the intervention. Dietary change was assessed using three 24-hour dietary recalls, which is the gold standard for assessing dietary change. Use of the multiple pass method helps reduce potential recall bias, though recall bias may persist. The decrease in energy intake (kcal) between baseline and 3- and 6-month follow-up was very substantial for the intervention group. Furthermore,

the mean number of kcals reported was low for these two time periods, especially given that the majority of participants were overweight or obese. Both of these factors suggest that recall bias may have been present. Previous studies have suggested that compared to non-Hispanic white women, Hispanic women may be more likely to underestimate energy intake when using standard dietary assessment tools.^{24,37} It is also possible that social desirability may have influenced the reporting of dietary intake. Participants in both intervention and control groups were given recommendations to increase fruit/vegetable intake and reduce fat intake. This may have caused participants to report dietary intake in a manner that would be viewed favorably by the interviewers. The study was designed to identify women with low fruit and vegetable intake using the brief Block Fruit/Vegetable/Fiber questionnaire. However, this method showed an under representation of fruit and vegetable intake compared to baseline intake based on 24-hour dietary recall assessment, which resulted in some women with >5 servings/day of baseline fruits/vegetables enrolling in the study. Other strengths are the validated measures used to assess health literacy and acculturation. The study is limited in that it was a single institution trial and the generalizability of the results to other populations of cancer survivors may be limited to other urban Hispanic subgroups of low socioeconomic status. Study participants were primarily of Dominican, Puerto Rican and Ecuadorian descent, which are groups that have specific dietary patterns compared to other Hispanic groups.³⁸ Future studies will need to test this approach in a more diverse population of cancer survivors.

CONCLUSION

The *¡Cocinar Para Su Salud!* study successfully identified an effective method to increase short-term fruit/vegetable intake among a diverse and underrepresented group of Hispanic breast cancer survivors. These dietary changes towards a healthier lifestyle have the potential to improve both breast cancer prognosis as well as cardiovascular and metabolic disease outcomes. The success of this intervention could inform the implementation of community-based nutrition education programs for Hispanic breast cancer survivors, and can also inform the design of future targeted dietary interventions to test whether these behavior changes can be sustained over time. This model of a curriculum-based, culturally-specific dietary change program has the potential to be widely disseminated to other groups. Future trials are planned to test this model in larger studies of Hispanic breast cancer survivors, as well as in studies of cancer survivors with other types of cancer.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
CONSORT diagram for randomized, controlled dietary intervention trial among a cohort of 70 Hispanic breast cancer survivors

Table 1Content, strategies and behavioral framework for the 9-session *¡Cocinar Para Su Salud!* curriculum^a

Session No.	Stage of change targeted	Session focus	Session content & strategies
1	Precontemplation Contemplation	Nutrition education Goal: Serious consideration of change	Tasks: Increase concern about the current pattern of eating by self- assessment compared to dietary cancer prevention guidelines; pros of change and benefits of fruits and vegetables; awareness of fat through food labels
2	Contemplation	Nutrition education Goal: Evaluation leading to decision to change	Tasks: Understanding pros and cons of change by comparing current eating to healthy sources of fat and protein; recommended portion sizes; low-fat options for animal foods and pre- prepared foods.
3	Contemplation	Hands-on cooking lesson Goal: Evaluation leading to decision to change	Tasks: Increase perceived benefits of adding fruits and vegetables to traditional dishes; healthy cooking methods and taste
4	Action	Nutrition education Goal: Action plan for change	Tasks: Make & implement plans to make a “Healthy Plate”; enhance self-efficacy for increasing fruit and vegetable intake
5	Action	Food shopping field trip to a grocery store Goal: Action plan for change	Tasks: Skills for healthy and budget- friendly shopping to enhance self- efficacy; implement plan for overall healthfulness of shopping choices
6	Action	Hands-on cooking lesson Goal: Action plan for change	Tasks: Implementing strategies for assembling daily meals according to recommended food portions; using high quality produce and protein; reducing saturated fat in animal protein; low-fat cooking methods
7	Maintenance	Nutrition education Goal: Sustaining change	Tasks: Understanding long-term health benefits of a healthy diet; planning in advance to avoid unhealthy behaviors
8	Maintenance	Food shopping field trip to a green market Goal: Sustaining change	Tasks: Implementing plans to buy fresh, high-quality produce in neighborhood; greenmarkets as an affordable place to shop
9	Maintenance	Hands-on cooking lesson Goal: Sustaining change	Tasks: Implementing plans to adapt traditional dishes with little or no red- meat; new dishes using legumes, whole grains, fruits and vegetables

^aBased on the Stages of Change Construct and Social Cognitive Theory strategies.

Table 2

Baseline demographic and clinical characteristics of a cohort of 70 Hispanic breast cancer survivors participating in a randomized, controlled dietary intervention trial

	Intervention ^a (n=34)	Control ^a (n=36)	Unadjusted P-value ^b
Demographic Characteristics			
Age (years)			0.21
Mean (SD)	55.1 (9.1)	58.0 (10.1)	
Range	40–78	36–81	
Race, n (%)			0.56
Black	7 (20.6)	11 (30.6)	
White	14 (41.2)	14 (38.9)	
Native American	2 (5.9)	0 (0.0)	
Mixed	5 (14.7)	6 (16.7)	
Nationality, n (%)			0.38
Colombian	0 (0.0)	1 (2.8)	
Cuban	0 (0.0)	1 (2.8)	
Dominican	24 (70.6)	30 (83.3)	
Ecuadorian	4 (11.8)	1 (2.8)	
El Salvadorian	1 (2.9)	0 (0.0)	
Honduran	0 (0.0)	1 (2.8)	
Mexican	1 (2.9)	0 (0.0)	
Puerto Rican	3 (8.9)	2 (5.6)	
Other	1 (2.9)	0 (0.0)	
Education, n (%)			
Less than high school	12 (35.3)	12 (33.3)	0.09
High school or GED	11 (32.4)	7 (19.4)	
Some college	5 (14.7)	15 (41.7)	
College degree or higher	5 (14.7)	2 (5.6)	
Employment status, n (%)			0.91
Full-time	10 (29.4)	8 (22.2)	
Part-time	5 (14.7)	5 (13.9)	
Retired	3 (8.8)	3 (8.3)	
Homemaker	5 (14.7)	9 (25.0)	
Unemployed	3 (8.8)	2 (5.6)	
Disabled	8 (23.5)	9 (25.0)	
Annual household income, n (%)			0.05
\$0 – \$15,000	18 (52.9)	26 (72.2)	
\$15,001 – \$30,000	6 (17.6)	7 (19.4)	
\$30,001 – \$60,000	5 (14.7)	1 (2.8)	
\$60,001+	0 (0.0)	1 (2.8)	
Currently in food assistance program, n (%)	22 (64.7)	19 (52.8)	0.31
Newest Vital Sign health literacy score (0–6)^c			0.13

	Intervention ^a (n=34)	Control ^a (n=36)	Unadjusted P-value ^b
Mean (SD)	1.1 (1.7)	1.8 (1.8)	
Median	0	1	
Range	0–5	0–5	
Acculturation Index (1–5)^d			0.46
Mean (SD)	1.7 (0.7)	1.5 (0.6)	
Range	1–3.6	1–3.0	
Clinical Characteristics			
Physical activity, mean minutes per week (SD)^e			
Total exercise	812.4 (691.0)	761.5 (692.8)	0.76
Low intensity exercise	298.7 (325.4)	232.3 (185.2)	0.30
Moderate intensity exercise	513.5 (577.1)	524.6 (598.7)	0.94
Vigorous intensity exercise	0.2 (1.3)	4.6 (19.5)	0.19
Years since diagnosis			0.51
Mean (SD)	3.6 (2.4)	3.1 (3.0)	
Median	3.5	2.8	
Range	0.7 – 11.8	0.3 – 15.6	
Postmenopausal at baseline, n (%)	23 (67.6)	26 (72.2)	0.57
Cancer stage, n (%)			0.31
Ductal carcinoma in situ (DCIS)	12 (35.3)	8 (22.2)	
I	11 (32.4)	16 (44.4)	
II	5 (14.7)	9 (25.0)	
III	4 (11.8)	1 (2.8)	
Locally advanced breast cancer (LABC)	2 (5.9)	1 (2.8)	
HER2^f positive tumor, n (%)	7 (31.8)	5 (17.9)	0.27
Endocrine receptor positive tumor, n (%)	31 (91.2)	30 (83.3)	0.48
Triple negative tumor, n (%)	2 (5.9)	3 (8.3)	0.56
Mastectomy, n (%)	15 (44.1)	16 (44.4)	0.98
Radiation therapy received, n (%)	24 (70.6)	20 (55.6)	0.19
Chemotherapy received, n (%)	15 (44.1)	19 (52.8)	0.47
Anti-hormonal therapy received, n (%)	25 (73.5)	26 (72.2)	0.55
Comorbidity index (0–20)^g			0.49
Mean (SD)	0.9 (1.4)	1.3 (1.4)	
Range	0–7	0–6	

^aTotals may not equal 100% due to missing/refused.

^bChi-Square and t-tests were used to calculate p-values for categorical and continuous data, respectively.

^cScore of 0–1 suggests high likelihood of limited literacy, score of 2–3 indicates the possibility of limited literacy, score of 4–6 almost always indicates adequate literacy (See reference #16).

^dThe Short Acculturation Scale for Hispanics (SASH) was used (range 1–5), with a score of 1 representing the lowest level of acculturation and a score of 5 representing the highest level of acculturation (See reference #14 &15).

^ePhysical activities categories were created by assigning intensity to specific types of activity. Low intensity activities included cooking, shopping, light cleaning, factory work, mechanic, restaurant work, or work involving walking. Moderate intensity activities included slow walking, work involving standing, taking care of children, moderate housework, brisk walking, dancing, homecare for an adult family member, and exercising gym or at home. Vigorous activities included moving boxes, heavy digging, farm chores, bicycling, and swimming for exercise (See reference #18).

^fHuman epidermal growth factor receptor 2

^gA comorbidity index was created by assigning a score of 1, 2, or 3 to each condition, and then summing the scores. Ulcers, diabetes, neurological problems, gastrointestinal problems, respiratory problems (shortness of breath and asthma), and cardiovascular risk factors (hypertension and high blood cholesterol) each received a score of 1; kidney disease, heart problems, chest pain, and physical limitations each received a score of 2; HIV/AIDS, and cancer other than breast cancer each received a score of 3.

Dietary changes from baseline to 3 and 6 months among a cohort of 70 Hispanic breast cancer survivors participating in a randomized, controlled dietary intervention trial

Table 3

										3 months				6 months			
Baseline										Change from baseline				Change from baseline			
n	Mean (SE) ^a	Adjusted P-Value ^b	n	Mean (SE) ^a	Adjusted P-Value ^b	n	Mean (SE) ^a	Adjusted P-Value ^b	n	Mean (SE) ^a	Adjusted P-Value ^b	n	Mean (SE) ^a	Adjusted P-Value ^b	n	Mean (SE) ^a	Adjusted P-Value ^b
Daily total caloric intake (kcal)										<0.001				<0.001			
Intervention	34	1573.8 (71.2)	31	880.3 (68.4)	−672.9 (79.2)	30	979.4 (74.6)	−562.9 (87.1)	30	979.4 (74.6)	−562.9 (87.1)	30	979.4 (74.6)	−562.9 (87.1)	30	979.4 (74.6)	−562.9 (87.1)
Control	36	1611.7 (69.2)	36	1517.3 (63.4)	−92.4 (73.5)	31	1527.5 (73.4)	−61.6 (85.7)	31	1527.5 (73.4)	−61.6 (85.7)	31	1527.5 (73.4)	−61.6 (85.7)	31	1527.5 (73.4)	−61.6 (85.7)
Daily fruit and vegetable intake^d																	
Fruits and vegetables (servings)										0.05				0.005			
Intervention	34	4.7 (0.5)	31	5.8 (0.4)	1.1 (0.5)	30	6.8 (0.4)	2.0 (0.5)	30	6.8 (0.4)	2.0 (0.5)	30	6.8 (0.4)	2.0 (0.5)	30	6.8 (0.4)	2.0 (0.5)
Control	36	5.8 (0.5)	36	5.6 (0.4)	−0.3 (0.5)	31	5.7 (0.4)	−0.1 (0.5)	31	5.7 (0.4)	−0.1 (0.5)	31	5.7 (0.4)	−0.1 (0.5)	31	5.7 (0.4)	−0.1 (0.5)
Fruits (servings)										0.92				0.30			
Intervention	34	2.2 (0.4)	31	2.4 (0.3)	0.1 (0.4)	30	2.7 (0.3)	0.3 (0.4)	30	2.7 (0.3)	0.3 (0.4)	30	2.7 (0.3)	0.3 (0.4)	30	2.7 (0.3)	0.3 (0.4)
Control	36	2.7 (0.4)	36	2.8 (0.2)	0.2 (0.4)	31	2.4 (0.3)	−0.3 (0.4)	31	2.4 (0.3)	−0.3 (0.4)	31	2.4 (0.3)	−0.3 (0.4)	31	2.4 (0.3)	−0.3 (0.4)
Vegetables (servings)										0.004				0.005			
Intervention	34	2.5 (0.3)	31	3.4 (0.3)	1.0 (0.3)	30	4.1 (0.3)	1.8 (0.4)	30	4.1 (0.3)	1.8 (0.4)	30	4.1 (0.3)	1.8 (0.4)	30	4.1 (0.3)	1.8 (0.4)
Control	36	3.2 (0.3)	36	2.8 (0.2)	−0.4 (0.3)	31	3.3 (0.3)	0.2 (0.4)	31	3.3 (0.3)	0.2 (0.4)	31	3.3 (0.3)	0.2 (0.4)	31	3.3 (0.3)	0.2 (0.4)
Daily intake of targeted fruits and vegetables, excluding juices, potatoes, fried vegetables and legumes										0.004				0.002			
Fruits and vegetables (servings)										0.34				0.04			
Intervention	34	3.4 (0.4)	31	5.3 (0.3)	2.0 (0.4)	30	6.0 (0.4)	2.7 (0.5)	30	6.0 (0.4)	2.7 (0.5)	30	6.0 (0.4)	2.7 (0.5)	30	6.0 (0.4)	2.7 (0.5)
Control	36	3.9 (0.4)	36	4.1 (0.3)	0.2 (0.4)	31	4.4 (0.4)	0.5 (0.5)	31	4.4 (0.4)	0.5 (0.5)	31	4.4 (0.4)	0.5 (0.5)	31	4.4 (0.4)	0.5 (0.5)
Fruits (servings)										0.29				0.04			
Intervention	34	1.4 (0.3)	31	2.2 (0.2)	0.8 (0.3)	30	2.3 (0.3)	0.8 (0.3)	30	2.3 (0.3)	0.8 (0.3)	30	2.3 (0.3)	0.8 (0.3)	30	2.3 (0.3)	0.8 (0.3)
Control	36	1.8 (0.3)	36	2.1 (0.2)	0.3 (0.3)	31	1.7 (0.3)	−0.1 (0.3)	31	1.7 (0.3)	−0.1 (0.3)	31	1.7 (0.3)	−0.1 (0.3)	31	1.7 (0.3)	−0.1 (0.3)
Vegetables (servings)										0.74				0.02			
Intervention	34	2.0 (0.3)	31	3.1 (0.2)	1.2 (0.3)	30	3.7 (0.3)	1.8 (0.3)	30	3.7 (0.3)	1.8 (0.3)	30	3.7 (0.3)	1.8 (0.3)	30	3.7 (0.3)	1.8 (0.3)
Control	36	2.1 (0.2)	36	2.0 (0.2)	−0.2 (0.3)	31	2.6 (0.3)	0.6 (0.3)	31	2.6 (0.3)	0.6 (0.3)	31	2.6 (0.3)	0.6 (0.3)	31	2.6 (0.3)	0.6 (0.3)
Daily fat intake										0.38				0.23			
Total fat, % of daily total energy										0.01				0.02			

Baseline			3 months			6 months		
	Baseline		n	Adjusted		Adjusted	Change from baseline	
	Adjusted	Adjusted		Mean (SE) ^a	P-Value ^b		Mean (SE) ^{a,c}	P-Value ^b
Intervention	34	28.5 (1.3)	31	21.3 (1.1)	-7.1 (1.5)	30	20.9 (1.2)	-7.5 (1.8)
Control	36	26.9 (1.3)	36	25.3 (1.0)	-1.6 (1.4)	31	22.5 (1.2)	-4.4 (1.8)
Saturated, % of daily total energy								0.14
Intervention	34	9.9 (0.6)	31	6 (0.5)	-3.8 (0.6)	30	6.6 (0.6)	-3.1 (0.8)
Control	36	8.9 (0.6)	36	8.6 (0.4)	-0.3 (0.6)	31	7.7 (0.6)	-1.5 (0.8)
Monounsaturated, % of daily total energy								0.71
Intervention	34	10.9 (0.7)	31	9.7 (0.5)	-1 (0.8)	30	8.4 (0.6)	-2.3 (0.9)
Control	36	10.2 (0.6)	36	9.5 (0.5)	-0.7 (0.7)	31	8.3 (0.6)	-1.8 (0.9)
Polyunsaturated, % of daily total energy								0.09
Intervention	34	5.2 (0.3)	31	4.8 (0.4)	-0.4 (0.4)	30	4.0 (0.3)	-1.3 (0.5)
Control	36	5.4 (0.3)	36	5.3 (0.4)	0.0 (0.4)	31	5.1 (0.3)	-0.1 (0.5)
Trans fats, % of daily total energy								0.63
Intervention	34	0.8 (0.1)	31	0.4 (0.1)	-0.3 (0.1)	30	0.5 (0.1)	-0.2 (0.1)
Control	36	0.8 (0.1)	36	0.6 (0.0)	-0.2 (0.1)	31	0.7 (0.1)	-0.1 (0.1)

^aEstimated marginal means adjusted for menopausal status and hormone replacement therapy use.

^bP-values calculated from linear regression models for the mean change from baseline comparing intervention and control groups, adjusted for menopausal status and hormone replacement therapy use.

^cThe changes from baseline to 3 and 6 months do not match the difference of the adjusted means for two reasons: 1) in some of the comparisons there are differences in the number of participants included, and 2) the regression model used to assess the differences between groups uses a calculated difference for each participant and thus the mean differences will be slightly different than the differences between the group means.

^dServing counts for both fruits and vegetables were compiled using the University of Minnesota Nutrition Data System for Research (NDSR) Nutrition Coordinating Center (NCC) food group serving count system.

Table 4

Change in anthropometric measures from baseline to 6 months among a cohort of 70 Hispanic breast cancer survivors participating in a randomized, controlled dietary intervention trial

	Baseline				6 months			
	n	Adjusted Mean (SE) ^a	Adjusted P-value ^b	n	Adjusted Mean (SE) ^a	Adjusted P-value ^b	Change from baseline	
							Adjusted Mean (SE) ^{a,c}	Adjusted P-value ^b
Weight (kg)			0.25			0.22		
Intervention	32	74 (2.7)		28	74.3 (3.7)		-2.2 (2.6)	-2.5% (3.6)
Control	35	78.4 (2.6)		27	81.3 (3.8)		2.3 (2.6)	3.8% (3.6)
BMI (kg/m²)			0.45			0.19		
Intervention	30	30.1 (1)		27	29.1 (1.5)		-1.1 (1.2)	-3.1% (3.8)
Control	35	31.1 (0.9)		26	33.2 (1.4)		1 (1.1)	3.8 % (3.7)
Waist circumference (cm)			0.18			0.05		
Intervention	31	93.1 (2.4)		25	94.9 (2.6)		-1.6 (1.2)	-1.3% (1.2)
Control	34	97.5 (2.3)		25	98.8 (2.6)		1.7 (1.2)	2.1% (1.2)
Hip circumference (cm)			0.09			0.72		
Intervention	31	106.6 (2.5)		25	109.2 (2.8)		-0.3 (1.9)	-0.2% (1.3)
Control	34	112.5 (2.4)		25	112.4 (2.8)		-1.2 (1.9)	-0.4% (1.3)
Waist/hip ratio			0.92			0.22		
Intervention	31	0.9 (0.0)		25	0.9 (0.0)		0.0 (0.0)	-0.9% (2.3)
Control	34	0.9 (0.0)		25	0.9 (0.0)		0.0 (0.0)	3.4% (2.3)

^aEstimated marginal means adjusted for menopausal status and hormone replacement therapy use.

^bP-values calculated from linear regression models for the mean change from baseline comparing intervention and control groups, adjusted for menopausal status and hormone replacement therapy use.

^cThe changes from baseline to 3 and 6 months do not match the difference of the adjusted means for two reasons: 1) in some of the comparisons there are differences in the number of participants included, and 2) the regression model used to assess the differences between groups uses a calculated difference for each participant and thus the mean differences will be slightly different than the differences between the group means.