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Original Research

Food environments are relevant to recruitment and adherence in dietary modification trials

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ABSTRACT

Few studies have examined the built environment's role in recruitment to and adherence in dietary intervention trials. Using data from a randomized dietary modification trial of urban Latina breast cancer survivors, we tested the hypotheses that neighborhood produce access could act as a potential barrier and/or facilitator to recruitment, and that a participant's produce availability would be associated with increased fruit/vegetable intake, one of the intervention's targets. Eligible women who lived within a higher produce environment had a non-significant trend towards being more likely to enroll in the trial. Among enrollees, women who had better neighborhood access to produce had a non-significant trend toward increasing fruit/vegetable consumption. As these were not a priori hypotheses to test, we consider these analyses to be hypothesis generating and not confirmatory. Results suggest that participants' food environment should be considered when recruiting to and assessing the adherence of dietary intervention studies.

1. Introduction

Dietary modification trials are an important tool used to assess the relationships between diet and disease because they allow investigators to manipulate dietary patterns and assess changes on a range of biomarker and clinical endpoints. Understanding the factors that affect both recruitment of eligible participants and adherence to the intervention allow investigators to more completely account for potential selection bias and effect measure modification in their trials. Knowledge of these external influences can lead to better designed and more externally valid interventions. Despite the growing body of evidence showing an association between an individual's food access within their neighborhood and fruit/vegetable consumption in adults [1,2], fruit/vegetable consumption in children [3], obesity levels [4–11], higher levels of dietary quality in pregnant women [12], differences in eating patterns [13–15], and the identification of the built environment as a predictor of

Abbreviations: CUMC, Columbia University Medical Center; DOHMH, Department of Health and Mental Hygiene; GIS, Geographic Information Systems; NCI, National Cancer Institute; NYC, New York City; NDSR, University of Minnesota Nutrition Data System for Research; SD, Standard Deviation; USDA, United States Department of Agriculture.

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adherence in physical activity interventions [16], few studies have examined the role of neighborhood food access in dietary modification trials.

Factors related to enrollment in dietary intervention trials and adherence to the interventions itself ultimately affect the interpretability and generalizability of trial results. Studies examining factors related to enrollment in clinical trials has largely focused on participant demographics [17–20], socioeconomic status [17,19], and participant feelings towards clinical trials [17,20]. To our knowledge, the association between an eligible participant's food environment and their decision to enroll in a dietary modification trial has not been examined. The literature on predictors of dietary intervention adherence has largely focused on demographic characteristics, such as participant education level, fruit and vegetable affordability [21–24], patient baseline dietary patterns [25], and whether or not the taste preferences of the participants overlap with the intervention nutrient end point [21,26,27]. A few studies have identified socio-cultural barriers to adherence such as decision making, cultural context [22,28], and familial support [28]. To our knowledge, only two studies have examined the food environment as a possible effect measure modifier in dietary interventions [29,30].

¡Cocinar Para Su Salud! (Cook For Your Health!) was a National Cancer Institute (NCI) funded randomized controlled trial that examined the effects of a community-based dietary modification intervention on fruit, vegetable and fat intake among Latina breast cancer survivors, the majority of whom lived in Northern Manhattan. The main trial results have been previously reported [31]. Briefly, the intervention group attended a short-term in-person 9-session dietary intervention program (24 hours in total) and the control group received written materials. After 6 months, the intervention group compared to the control group reported an increase in targeted fruits and vegetables (+2.7 servings vs. +0.5 servings, P = 0.002), a nonsignificant decrease in percent calories from fat (–7.5% vs. -4.4%; P = 0.23), and a nonsignificant decrease in weight (–2.5 kg vs. +3.8 kg; P = 0.22). Using data from this trial, we tested the hypotheses that a participant's food environment, and specifically their access to produce, could pose a barrier to participation in a dietary intervention trial, and that a participant's produce availability would be associated with adherence to the trial. To test these hypotheses we compared characteristics of eligible women who did and did not enroll in the trial, and among participants randomized to the intervention group we examined adherence to the intervention by a participant's local food environment. As these were not a priori hypotheses to test, we consider these analyses to be hypothesis generating and not confirmatory.

2. Methods and materials

2.1. Participant recruitment, consent and enrollment

¡Cocinar Para Su Salud! was a culturally tailored randomized controlled trial comparing the effects of a nine-session (24 hours over 12 weeks) dietary intervention vs. standard of care written materials on dietary intake for cancer survivors [31]. Spanish-speaking patients from the Columbia University Medical Center (CUMC) Breast Oncology Clinic with non-metastatic stage 0-III cancer were recruited by a native Spanish speaker between January 2011 and March 2012. Eligibility criteria were defined as: ≥21 years of age, Spanish language fluency and Hispanic ethnicity, controlled comorbidities if present, non-smoker, fewer than five servings of fruit and vegetables daily as measured by the Block Fruit and Vegetable Screener, and no current involvement with a dietary change program. Trial eligibility was initially assessed by medical record review and participants provided written informed consent to be further screened for trial eligibility. An interviewer administered screening interview was conducted by telephone or in person to obtain data on participant demographics and treatment history. Patients who met the eligibility criteria were invited to participate in the trial and were scheduled for a baseline interview and a clinic visit to assess detailed demographic data, medical history, reproductive history, family history, demographics, physical activity, medication use, acculturation, anthropomorphic measures, physical examination and 24 hour dietary recall. Participants were randomized into the trial following the baseline clinic visit. Participants provided written informed consent and the study was approved by the Columbia University Medical Center and Columbia University Teachers College Institutional Review Boards.

A total of 102 women were screened for the trial and were eligible for participation. Ultimately, 70 women enrolled in the trial. Twenty-two percent (n = 21) of the participants screened reported that family members (children, parents or "someone else") were doing the majority of their shopping. Since many of these family members were using personal cars to procure the groceries, women who did not do their own grocery shopping were excluded from these analyses in order to isolate the effect of the immediate food environment on shopping decisions.

2.2. Intervention

Development of the intervention has been described in detail elsewhere [32]. Briefly, eligible participants were randomized into either a nine-session intervention program or the control group of written materials detailing dietary guidelines for cancer survivors. The nine sessions were tailored specifically for the dietary habits of Hispanic populations with the goal of decreasing dietary fat and increasing fruit/vegetable consumption. The sessions included nutrition education, hands-on cooking classes and food shopping field trips. The control group received standard care, a 22-page Spanish language written dietary recommendation booklet for breast cancer survivors [33]. The entire intervention was conducted in Spanish and all study staff were bilingual (Spanish/English).

2.3. Data collection

2.3.1. Dietary data

The Block Fruit, Vegetable and Fiber Screener was used during the screening interview to determine if patients met the eligibility criterion of consuming fewer than 5 servings of fruits and vegetables daily [34]. Afterwards, enrolled participants' diets were assessed at baseline, 3 months and