Study Title: WIC-Based Intervention to Promote Healthy Eating Among Low-Income Mothers
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Objectives

This study examined the preliminary efficacy of a novel, theory-driven intervention designed for adults served by the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Primary outcomes were vegetable intake (objectively assessed using dermal carotenoids as a biomarker of intake and via self-report) and the redemption of WIC Farmers' Market Nutrition Program (FMNP) vouchers for fruit and vegetable purchases at farmers' markets (objectively assessed using data provided by WIC). Potential hypothesized mediators of intervention effects were vegetable-related knowledge, attitudes, and behaviors; physical activity, and weight status. Intervention effects on the redemption of WIC cash value vouchers (CVV) at farmers' markets, participant satisfaction with the program, and the cost-effectiveness of the intervention also were examined. The CVV are issued monthly by WIC for fruit and vegetable purchases and are redeemable at farmers' markets in New Jersey, the location of the study.

Setting, Design, and Sample

The setting for the research was a large, New Jersey-based WIC agency located in a densely populated primarily Hispanic urban area. The intervention was evaluated in three of the agency's 17 sites selected based on similarity in size and the demographics of participants served (one randomized to the intervention study group and two to the control group). As the intervention was delivered at the site level, randomization was by site to prevent contamination of the control group.

Inclusion criteria were 1) English- or Spanish-speaking adult, 2) FMNP voucher recipient or caregiver of a child voucher recipient, 3) no known restrictions on food intake, 4) not less than 3 months from expected delivery date (if pregnant), and 5) eligible to receive WIC benefits for at least 6 months after study entry. Recruitment occurred from June 3, 2019, to August 1, 2019. Across sites, trained bilingual English/Spanish-speaking research staff contacted participants considered eligible to receive FMNP vouchers based on information provided by WIC by telephone prior to forthcoming appointments, provided a description of the study, and confirmed eligibility. Interested adults were orally administered an outcome battery of self-report measures. During appointments, biometric measures (height, weight, and carotenoid levels) were taken. Participants also were recruited from the WIC clinic where they completed all measures in person. All participants provided informed consent verbally, prior to completing telephone assessments, and in writing prior to completing in-person assessments. Thereafter, a WIC administrator confirmed whether adults completing all assessments had received FMNP vouchers. Those who did not were informed that they were ineligible and were thanked for their involvement.

In total, 297 adults were enrolled. Participants enrolled at the intervention site (n = 160) received routine services provided by WIC and the intervention. Those enrolled at control sites (n = 137) received routine services only. Across sites, all participants were contacted to complete follow-up measures at mid- and post-intervention (3 and 6 months post-baseline, respectively). As at baseline, research staff contacted participants by telephone prior to forthcoming appointments and orally administered the outcome battery; during appointments, biometric measures were taken. To enhance retention, across sites, research staff mailed appointment reminders to participants and confirmed appointments via telephone one day in advance, maintained multiple contacts for participants, and updated participants' contact information at each assessment. Honoraria, gift cards redeemable at local supermarkets and discount chain stores, also were provided to participants for completing successive assessments. Participants received a $10 honorarium at baseline and at mid-intervention; to enhance response rates, the amount was increased to $20 at post-intervention (participants received up to $40 in honoraria in total). For self-report data assessed via the outcome battery, 273 participants completed at least one post-baseline assessment

(143 participants in the intervention group and 130 in the control group); for biometric measures, the corresponding figure was 261 (137 in the intervention group and 124 in the control group).

Intervention

Designed to address individual and broader systems-level influences on vegetable intake, the intervention was conceptually grounded in the Social Ecological Model and Social Cognitive Theory.[1] According to the Social Ecological Model, behavior is shaped by influences operating at multiple levels, i.e., intrapersonal and interpersonal factors, community and organizational factors, and public policies.[2] Social Cognitive Theory emphasizes targeting the environment (factors external to a person), behavioral capacity (knowledge and skills to perform a behavior), and self-efficacy (confidence in the ability to perform a behavior) using self-control strategies such as monitoring and feedback to regulate behavior, observational learning (the acquisition of behaviors by observing outcomes of others' behavior, ideally, credible and relatable role models); and reinforcement (incentives, rewards, and feedback) to increase the likelihood of a behavior.[3,4] The program consisted of 1) a WIC-based farmers' market to improve community access to vegetables, and among those purchasing items at the market, home vegetable availability; 2) behaviorally focused instruction to enhance social support for vegetable consumption and build vegetable-related knowledge, skills, and self-efficacy; 3) field trips to an area farmers' market to further improve vegetable access, provide opportunities for experiential and hands-on learning, and enable participants to apply knowledge and skills learned at the WIC-based market to a real-world setting; 4) telephone coaching and support before and after trips to facilitate plans to incorporate vegetables into daily meals, 5) recipe demonstrations and tastings to build vegetable knowledge, preparation skills, and taste preferences; and 6) handouts to reinforce vegetable knowledge and preparation skills. The program logic model is shown in the figure.

The WIC-based market was implemented at the intervention site in the summer of 2019 during the FMNP voucher issuance period. Participants presenting for appointments (during which they would receive FMNP vouchers) were directed to wait in a classroom with the market. Nutrition educators provided group-based instruction to participants while waiting for appointments, conducted recipe demonstrations and tastings (in total, 3 recipes were demonstrated), and instructed participants to return to the classroom after appointments to receive additional instruction and a recipe pack containing handouts and the ingredients for one of the recipes to try at home. Participants also learned that they had the option to purchase fruits and vegetables at the WIC-based market with their FMNP vouchers. Nutrition educators provided personalized, 1:1 instruction to participants returning to the classroom after appointments.

Thereafter, participants completed up to three field trips to the area farmers' market (one each in September, October, and November). The same individuals who delivered nutrition education at the WIC-based market scheduled the trips and provided group-based instruction to participants during trips. At the market, the educators conducted recipe demonstrations and tastings (3 recipes per trip, differing each month), distributed recipe packs containing the ingredients for one of the recipes, and provided 1:1 instruction to participants. The educators also provided telephone coaching and support to participants before and after trips. The 5-month intervention was implemented between July 1, 2019, and November 30, 2019.

Measures

At baseline, participants reported their age, race, ethnicity, nativity, language preference and years in the US (if foreign born), pregnancy and breastfeeding status, educational attainment, car ownership and access, supplement use, smoking status, and past 7-day exposure to

secondhand smoke. Food security status was assessed with an item from the Household Food Security Survey Module ("Have you or other adults in your household worried whether your food would run out before you got money to buy more?").[5] Participants also completed a validated measure of social desirability trait, the tendency to respond to self-report measures in a manner consistent with expected norms.[6] As children aged 2 to 5 years were eligible to receive FMNP vouchers, a measure of the number of children per household aged 2 to 5 years was constructed based on FMNP voucher data provided by WIC.

Vegetable intake was objectively measured with pressure-mediated reflection spectroscopy, a safe, reliable, and valid method for noninvasively assessing dermal carotenoids as a biomarker of intake.[7] Carotenoid levels were assessed with a portable device, the Veggie Meter™ (Longevity Link Inc., Salt Lake City, UT), by scanning the tip of the finger. Scans were conducted in triplicate and the average of the three scans was recorded. Scores can range from zero to 800, with higher scores indicating higher dermal carotenoid levels. Vegetable intake also was assessed via self-report with one of two items in a brief fruit and vegetable screener developed by the National Cancer Institute ("How many cups of vegetables [including 100% vegetable juice] do you eat or drink each day?").[8] To facilitate the estimation of food portions, participants were told that a cup was about the size of their fist.[9]

FMNP voucher redemption was objectively assessed once at the end of the voucher redemption period (June 1 to November 30, 2019) using data provided by WIC. WIC reported whether participants redeemed any vouchers (yes/no) over this period.

Knowledge of vegetable intake recommendations was assessed with an item from the Food Attitudes and Behaviors Survey.[10] Based on their responses, participants were classified as knowledgeable of the recommended cups/day of vegetables (yes/no) as per the My Plate amounts for women aged 19 to 50 years.[11]

Home vegetable availability was measured with the Home Health Survey, shown to have moderate reliability and validity.[12] Participants responded to items querying whether they had any fresh, canned, and frozen vegetables at home (yes/no). Those responding affirmatively were asked to report which vegetables they had at home. Two measures of availability were constructed based on the responses: 1) the quantity or total number of vegetables at home, and 2) the variety or number of different items at home.

Vegetable taste preferences were assessed with a single item, "Overall, how much do you like the taste of vegetables?" Responses were on a 7-point scale ranging from not at all (1) to a lot (7). Higher scores indicated greater taste preferences.

Social support for vegetable consumption was assessed with the item, "How much would you say people in your life support you to eat vegetables?" Responses were on a 7-point scale ranging from not at all (1) to a lot (7). Higher scores indicated greater social support.

Vegetable preparation practices were assessed with three items from the Project EAT-II survey.[13] Participants reported how often they performed the following behaviors in the past month: 1) bought fresh vegetables, 2) prepared a green salad, and 3) prepared a dinner with vegetables. Responses were on a 5-point scale ranging from never (1) to more than once a week (5).

Vegetable preparation skills were assessed with the following item: "How would you rate your overall skill in preparing vegetables?" Responses were on a 7-point scale ranging from poor (1) to excellent (7). Higher scores indicated greater preparation skills.

Self-efficacy for vegetable consumption was assessed with an adapted version of a 5-item measure of self-efficacy for fruit and vegetable consumption.[14] The measure was adapted by revising items referencing fruits and vegetables to reference vegetables only (sample item: "I feel I can prepare recipes with vegetables.").[14] Responses were on a 4-point scale ranging from strongly disagree (1) to strongly agree (4); higher scores indicated greater self-efficacy.

Physical activity was operationalized as meeting current physical activity guidelines and was assessed with a validated 2-item measure.[15] Participants reported the frequency and duration of moderate and vigorous intensity physical activity, respectively, in a typical week. Item responses were assigned point values and summed to derive a total score. Score ranges were used to classify participants as meeting physical activity guidelines (yes/no).[15]

Weight status was measured as body mass index (BMI), calculated as weight in kilograms divided by height in square meters.[16] Height and weight were measured with participants wearing light clothing without shoes using standardized methods and equipment (Seca 876 scale and Seca 213 stadiometer [Seca Corp., Chino, CA]).[17]

Cash value voucher redemption was assessed using data provided by WIC and was tracked over the same period as FMNP voucher redemption (June 1, 2019, to November 30, 2019). WIC reported whether participants redeemed any CVV at farmers' markets (yes/no) over this period.

Satisfaction with the intervention was assessed at post-intervention among participants who received the intervention. A single item measure (with response options on a 7-point scale ranging from very dissatisfied [1] to very satisfied [7]) was used to assess overall satisfaction with the program. Participants also completed a 5-item satisfaction measure developed by the investigators (sample item: "The program was interesting;" Cronbach's $\alpha = 0.90$). Responses were on a 7-point scale ranging from strongly disagree (1) to strongly agree (7). Ratings were averaged across items to derive a total score. Higher scores indicated greater satisfaction. Participants also responded to open-ended items on what was liked most and least about the program, what, if anything, could be done to improve it; and the most important thing learned in the program.

Hypotheses

Primary (Outcome Evaluation)

H_1: At mid- and post-intervention, greater improvements in vegetable intake and FMNP voucher redemption will be found among participants who receive the intervention relative to those who do not.

Secondary (Mediation Analyses)

H_2: Program effects on vegetable intake will be mediated by improvements in vegetable-related knowledge, attitudes, and behaviors; physical activity, and weight status.

Exploratory Aims

1. To evaluate intervention effects on the redemption of CVV at farmers' markets.
2. To examine satisfaction with the intervention among participants who receive it.
3. To determine the cost-effectiveness of the intervention.

Intervention Effects on Primary Outcomes and Potential Mediators

Linear mixed-effects models were used to relate two repeated measures of primary outcomes and potential mediators to time, trial arm, and a time-by-arm interaction. Covariates included baseline measures of each outcome and prognostic factors or potential influences on intake. A common set of prognostic factors was identified for inclusion across analyses, i.e., age, race, breastfeeding status, and exposure to secondhand smoke. Supplement use, a potential confounder of carotenoid data, and social desirability trait, shown to influence self-reports of behavior, also were included in analyses of objectively measured and self-reported vegetable intake, respectively. Intervention effects on binary measures of knowledge of vegetable intake recommendations and meeting physical activity guidelines were examined with generalized linear mixed models with binary error distributions. In addition to tests of the significance of differences between least square means by trial arm at each time point, 95% confidence intervals were estimated for the differences. To quantify the magnitude of between-group differences, adjusted Cohen's *d* was calculated as the difference between least square means divided by the square root of the residual variance.

Logistic regression analysis was used to relate FMNP voucher redemption to study arm. The analysis was adjusted for the aforementioned covariates, i.e., age, race, breastfeeding status, and exposure to secondhand smoke. Odds ratios (ORs) were estimated with 95% confidence intervals. For FMNP voucher redemption, effect size was measured using ORs, where 1.5 is a small effect, 2.5 is a medium effect, and 4 is a large effect.

Exploratory Analyses

Preliminary analyses revealed that 12 participants redeemed CVV at farmers' markets, all in the intervention arm. Thus, a formal analysis of intervention effects on CVV redemption was not conducted. Mean ratings on measures of satisfaction with the intervention (on a 7-point scale) were computed. Scores at or above 5.0 were considered evidence of a high degree of satisfaction. Responses to open-ended items were examined with thematic analysis. Total and per participant intervention costs and cost-effectiveness ratios (expressed as cost per intervention effect) were estimated in 2019 US dollars over a 6-month period from the perspective of the agency implementing the intervention. Although not originally planned, we also examined the relationships between measures of vegetable intake and potential hypothesized mediators at baseline, and screened baseline values of the mediators for a possible ceiling effect.

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