

STUDY PROTOCOL

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A randomized controlled trial of nutrition education to promote farmers' market fruit and vegetable purchases and consumption among women enrolled in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC): rationale and design of the WIC Fresh Start program

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Abstract

Background: This report describes the protocol guiding the design and evaluation of a theory-driven, web-based lesson to promote farmers' market fruit and vegetable (FV) purchases and consumption among women enrolled in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). Designed to leverage vouchers provided to WIC participants for FV purchases through the Farmers' Market Nutrition Program (FMNP) and monthly cash value vouchers (CVVs) redeemable at farmers' markets, the lesson is conceptually grounded in formative research on knowledge, attitudes and skills influencing farmers' market FV purchases and consumption and theoretical understanding of approaches for modifying them.

Methods/Design: The setting is a large WIC agency serving three New Jersey counties. Separate samples of women were recruited to participate in 1) focus groups for guiding lesson content development ($N = 56$) and pretesting the resulting content ($N = 52$), 2) cognitive testing to assess the clarity and interpretability of items and response formats in measures of knowledge, attitudes and skills developed for the study ($N = 15$), 3) one-on-one sessions to assess reactions to initial versions of video segments developed for the lesson ($N = 20$), and 4) the outcome evaluation ($N = 744$). Stratified based on FMNP voucher receipt, participants are randomized to receive the lesson or existing online health education. Outcome measures (administered orally to reduce literacy demands of the response task) are completed at pretest (immediately before the lesson), posttest (2 weeks after the lesson), and 3 and 6 months after posttesting. Short- and long-term lesson effects on FV intake, FMNP voucher redemption and the redemption of CVVs at farmers' markets will be evaluated. Evidence for mediation by knowledge, attitudes and skills of lesson effects on FV intake and voucher redemption, dose-response relationships, and user satisfaction with the lesson also will be examined.

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Discussion: Theory-driven, web-based nutrition education expressly designed for WIC to promote farmers' market use is lacking. The WIC Fresh Start program addresses the paucity of programs of this type. Findings will advance understanding of effective approaches for promoting farmers' market FV purchases and consumption among WIC participants.

Trial Registration: NCT02565706 (registered September 30, 2015)

Keywords: Randomized controlled trial, Farmers' market, Farmers' market nutrition program, Cash value voucher, Fruits, Vegetables, Income, WIC program, Internet

Background

Fruit and vegetable (FV) consumption is associated with decreased incidence of and mortality from cardiovascular diseases, cancer, diabetes and obesity [1–3]; yet, less than 5 % of U.S. adults consume recommended amounts of FVs [4]. Low income is a risk factor for low FV intake [5–7], highlighting the need for dietary intervention in low-income groups. Low-income women of childbearing age may benefit disproportionately from intervention as optimal dietary intake influences nutritional status and has implications for neonatal and infant development [8].

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) is designed to safeguard the health of low-income pregnant and postpartum women, infants and children up to 5 years who are at nutrition risk by providing healthy foods to supplement diets (via WIC food packages), nutrition education, and counseling and referrals to other health, welfare and social services [9]. The program is unique in that it provides nutrition education to all participants and to caregivers of infant and child participants [10]. WIC serves over 9 million mothers and young children annually, over 1.5 million pregnant and breastfeeding mothers, more than half of America's infants and 25 % of its children aged 1–5 years [11], providing an unparalleled opportunity to promote FV consumption through effective nutrition education.

In 1992, Congress established the WIC Farmers' Market Nutrition Program (FMNP) to provide fresh, unprepared, locally grown FVs to WIC participants and to raise awareness, use of, and sales at farmers' markets and roadside stands [12]. The program provides WIC participants vouchers redeemable for 10–\$30 of produce from farmers authorized to accept the vouchers during the farmers' market season (typically June through November). [12]. Previous research has shown that WIC participants who receive FMNP vouchers have higher vegetable intake and higher intake of FVs combined relative to those who do not [13–16]. Farmers' market use is greater among WIC participants who previously redeemed FMNP vouchers as compared to those who did not receive or redeem them [17]. Relative to vouchers alone, stronger FMNP effects on FV intake are

found when FMNP vouchers are supplemented with nutrition education [18].

In 2009, changes to the WIC food package included the addition of a cash value voucher (CVV) for FV purchases [19]. CVVs are valued at \$10 for women and \$6 for children [19]. WIC state agencies have the option to approve CVVs for use at farmers' markets [19]; roughly one-fourth (23 %) of agencies do so [20]. Whereas FMNP vouchers are issued on a seasonal basis and not every family is guaranteed to receive them due to funding constraints, CVVs are issued monthly to all WIC participants [21]. As such, CVVs afford WIC participants ongoing opportunities to purchase FVs at farmers' markets in states approving their use at these venues.

Despite the promise of FMNP vouchers and CVVs for improving access to fresh FVs among WIC participants, the FMNP voucher redemption rate is low (59 % nationwide in 2014) [22]. Because the USDA tracks CVV use in the aggregate regardless of where vouchers are redeemed, national-level data on CVV redemption at farmers' markets are lacking [20]. Among states reporting this information, the rate of redemption is less than 1 % [20]. Interventions to improve advertising, outreach and coordination among key stakeholders (e.g., farmers, government representatives and farmers' market managers), show promise for improving CVV redemption at farmers' markets [20]. Far less is known, however, about the utility of nutrition education for accomplishing this goal. Evidence of improved FMNP voucher redemption when FMNP vouchers are supplemented with nutrition education seems to suggest the promise of nutrition education for also increasing the redemption of CVVs at farmers' markets [18]. Yet, nutrition education expressly designed for WIC to encourage farmers' market use is lacking. This report describes the protocol guiding the design and evaluation of the WIC Fresh Start program, a theory-driven, web-based nutrition education lesson to promote farmers' market FV purchases and consumption among WIC participants. The project is a partnership between a university-based researcher and New Jersey state and local WIC agency representatives. New Jersey is among the states authorizing the redemption of CVVs at farmers' markets.

Research objectives

1. Develop a theory-driven, web-based nutrition education lesson to promote farmers' market FV purchases and consumption among WIC participants.
2. Evaluate lesson effects on FV intake, FMNP voucher redemption and redemption of CVVs at farmers' markets immediately following and 3 and 6 months after the lesson in a randomized four-arm design (lesson, lesson + FMNP vouchers, existing online health education, and existing online health education + FMNP vouchers).

Study hypotheses

Primary (outcome evaluation)

1. Women in the lesson + FMNP vouchers condition will have higher FV intake at posttest and follow-up measurements relative to women in the three other conditions.
2. Women who receive the lesson will have higher FV intake at posttest and follow-up measurements relative to women who receive existing online health education.
3. Women who receive FMNP vouchers will have higher FV intake at posttest and follow-up measurements relative to women who do not receive FMNP vouchers.
4. At posttest and follow-up measurements, the redemption of CVVs at farmers' markets will be higher among women who receive the lesson relative to women who receive existing online health education.
5. FMNP voucher recipients who receive the lesson will have higher voucher redemption at posttest and follow-up measurements relative to those who receive existing online health education.

Secondary (process evaluation)

6. Lesson effects on FV intake and voucher redemption will be mediated by improvements in targeted knowledge, attitudes, and skills.
7. Receipt of more of the lesson will be associated with more favorable outcomes.
8. User satisfaction will be higher among women who receive the lesson relative to women who receive existing online health education.

Methods/design

Trial design

The evaluation employs a four-arm, longitudinal randomized design. Stratified based on FMNP voucher receipt, participants are orally administered a pretest and randomized to receive the lesson or existing online

health education at the collaborating WIC agency. Two weeks after the lesson, participants are contacted by telephone to complete the posttest. Telephone-administered follow-up assessments are conducted 3 and 6 months after posttesting.

Trial status

At the time of manuscript submission, recruitment has been completed. Data collection has started and is ongoing.

Setting

The setting is a large WIC agency serving 21,500 participants across three New Jersey counties monthly. All study data are being collected at this location.

Participants and procedure

Pregnant and postpartum WIC participants and female caregivers of infant/child participants (i.e., those eligible to receive WIC nutrition education) with no known restrictions on food intake who are not high-risk are eligible for the study. Trained research assistants (RAs) screened women for eligibility when presenting for services. Eligible women received oral and written descriptions of the study and provided informed written consent prior to their study involvement. The study was approved by the William Paterson University Institutional Review Board for Human Subject Research (2014–368) and registered with ClinicalTrials.gov (NCT02565706). It is being conducted and will be reported in accordance with CONSORT guidelines [23]. Recruitment for the lesson development phase of the project (research objective 1) began in July 2014. Enrollment for the outcome evaluation (research objective 2) began in June 2015.

Sample size and power

The primary outcome is FV intake. Two dimensions are assessed: frequency of intake (times per day FVs are consumed) and quantity of intake (cups per day of FVs consumed). Preliminary data on FV servings per day were available and were used to estimate the standardized effect size needed for power calculations. Systematic reviews of FV interventions reveal post-intervention between-group differences in FV intake of .42–2.5 servings/day in minority and low-income adults [24, 25]. Conservatively, the study is powered to detect a .60 serving/day difference. Analyses for testing hypotheses 1–3 include covariance adjustment for pretest FV consumption. Assuming a population standard deviation of 1.5 servings and .20 correlation between pretest and posttest measures of intake (based on research in WIC samples) [13, 26], 380 women (95 per arm) are needed to detect a difference of this magnitude in pairwise posttest

comparisons by arm (standardized effect size = .41). When follow-up measurements are considered, the error variance is further reduced due to 3 repeated measures and pretest covariance adjustment. The sample is sufficiently large to detect an effect size of .26 or greater in longitudinal analyses. Allowing for 40 % attrition from pretest to final follow-up (based on rates of attrition in other WIC samples) [18, 27], the sample size was inflated a priori by 1.66 (1/.60). This inflation yielded a sample size of 630 at time of recruitment. As sufficient numbers of women in the FMNP stratum were not enrolled during the recruitment phase of the study, the phase was extended by 2 weeks. In total, 744 women were enrolled.

Randomization sequence generation and allocation concealment

One of the investigators generated a binary randomization sequence using SAS® (version 9.4, 2013, Cary NC). Blinded to group assignment, RAs recruited participants and recorded their names on a form. Information on whether the participant was allocated to receive the lesson or existing online health education was preprinted in a column adjacent to the space provided for recording names and was concealed by a cover page. The recruiting RA assigned the participant to a second RA who met with the participant in a 1:1 session during which the consent form was reviewed/completed, the pretest was administered, and the participant watched an online lesson. The enrolling RA informed the second RA of whether the participant would receive the lesson or choose from among existing online lessons at the start of the 1:1 session. RAs are unaware of which lesson is being evaluated in the study.

Intervention

Overview

The intervention is an online lesson to promote farmers' market FV purchases and consumption. Women in the control group complete any of seven existing online lessons (lessons are available on breastfeeding, being active, fruits and vegetables, calcium, cholesterol, oral health and iron). The lesson comprises three modules, each consisting of 1) behavior change content presented through a video segment featuring WIC participants, and 2) an interactive activity to build targeted knowledge, attitudes, and skills. Existing online lessons consist of an introductory segment presented with online text and graphics. After reading this material, women have the option to complete one of four lesson activities. The activities provide opportunities for women to read further on the topic and are designed to reinforce key points of the lesson.

Preliminary work

Formative research with state and local WIC agency representatives ($N = 5$) and participants served by the collaborating WIC agency ($N = 54$) identified influences on farmers' market FV purchases and consumption that are the focus of the lesson, i.e., lack of knowledge of the FMNP and WIC-authorized farmers' markets (locations, hours of operation and transportation options to markets), negative attitudes towards farmers' market FVs (including farmers' market FV food safety concerns), limited awareness of locally grown, seasonal FVs (items that are in season and selection, storage and parts eaten of the items), limited asking skills (extent of asking farmers about their participation in the FMNP and their produce), limited FV food safety and farmers' market FV preparation skills, and low positive outcome expectations for consuming locally grown FVs.

Given the advantages Internet interventions afford (e.g., scalability or accessibility by many people, simultaneously and repeatedly; uniformity of delivery; the ability to provide customized, engaging and interactive content and low delivery costs) [28, 29] and interest in designing a resource that would fit well within WIC clinic operations, the lesson is delivered online. In 2009, the New Jersey WIC program launched an interactive website offering nutrition and health lessons [30]. In 2011, computer kiosks were placed in all local agency administrative offices to enable WIC participants to complete lessons while in the WIC clinic [30]. The expansion of topics is one component of the state's plan for enhancing revisit rates to the website [30].

Women from the collaborating WIC agency were primarily African American (45 %) and Hispanic (44 %), with 63 % of Hispanics reporting Spanish as the primary language spoken at home. In light of the high proportion of participants speaking Spanish as their primary language, English- and Spanish-language versions of the lesson were developed. Women had less formal education for their age group than the U.S. population average (67 % had earned a high school diploma; 19 % had not completed high school) [31]; as such, they are likely to experience low health literacy [32]. Content delivery is therefore through short video segments and audio output to maximize accessibility for learners with low literacy and numeracy skills [33]. Because lesson activities require user input, to maximize comprehension, audio instruction on the completion of activities is provided, questions and responses are read aloud as they appear on the screen and viewers can hear them again by clicking on audio icons adjacent to on-screen text. To enhance community ownership of and the credibility and relevance of messages, WIC participants were engaged as full partners in the development of the lesson (as described below) and the delivery of content (videos

feature participants). Owing to the strong oral tradition of the primarily African American and Hispanic women for whom the lesson is developed, key messages are conveyed through participant experiential narratives or first-hand stories [34–36].

Six versions of the lesson were planned (one for each month of the farmers' market season featuring locally grown, seasonal items). This will allow women presenting for nutrition education in a particular month to receive information on FVs they are likely to find at farmers' markets at that time of year. For the current study, the lesson for the month of July was developed.

In a serial format or single narrative spanning the three modules, WIC participants featured in the lesson discuss challenges that prevented them from purchasing and consuming farmers' market FVs (exposition and beginning of conflict), events serving as a catalyst for change (complication and climax), ways they overcame the challenges and strategies (education and skills training) for helping viewers do the same (resolution) [37]. Lesson modules, goals (targeted outcome changes), content and activities are summarized below.

Lesson modules

Farm fresh Goal: To increase knowledge of the FMNP and WIC-authorized farmers' markets and promote favorable attitudes towards farmers' market FVs. Content: Viewers are introduced to three WIC participants shown waiting for a nutrition class at the collaborating WIC agency. Each shares "her story" (reasons she did not shop at farmers' markets, something that happened to change her mind about this, and lessons learned that she will share with viewers). Thereafter, the first participant discusses common misperceptions about farmers' market FVs and provides corrective feedback based on her experiences. Activity: Viewers enter their zip code into a Farmers' Market Locator Tool and are provided with information on the three WIC-authorized markets nearest to their home. They have the option to search in another zip code area and can email themselves information about the different markets.

Market smarts Goal: To promote positive outcome expectations for consuming locally grown FVs and improve farmers' market FV knowledge and asking skills. Content: Featuring the second WIC participant filmed at a local farmers' market, the participant discusses FVs that are in season, reasons to choose locally grown seasonal items, and featured items (selection, storage and parts eaten of three locally grown, seasonal items). Throughout the discussion, the participant emphasizes the importance of getting to know local farmers. A local farmer also is featured. The farmer discusses his

motivation for selling his produce at the market (to educate consumers about different FVs that are locally available), his appreciation for having customers ask about the FVs he grows, and his hope that WIC participants will take advantage of the fresh FVs local farmers have to offer, noting that he and other farmers are glad to work with WIC participants and realize how important it is for women and children to have high quality FVs. Activity: Market Smarts Quiz (viewers respond to true/false items about featured items).

In the kitchen Goal: To improve FV food safety and preparation skills. Content: Featuring the third WIC participant shown in a kitchen, the participant demonstrates the safe handling of FVs, including tips specific to the three items featured in Market Smarts. Video demonstrations of recipes for preparing the items also are shown. Only recipes that can be made with other items in the WIC food package are presented. Activity: Viewers rehearse steps for making a FV recipe by placing, in the correct order, picture cards depicting the different recipe steps.

Immediately after completing the lesson, women receive a packet of handouts highlighting information presented in the lesson. One, two, and three months after the lesson they receive a follow-up email that links to a video featuring WIC participants shown in the lesson. Participants "check-in" with viewers to ask if they have been to a farmers' market, reinforce key messages presented in the lesson and demonstrate a new recipe for preparing a featured FV item.

Conceptual model

The lesson is grounded in formative research on knowledge, attitudes and skills influencing farmers' market FV purchases and consumption and theoretical understanding of approaches to modifying them. Social Cognitive Theory supports leveraging environmental FV resources (i.e., promoting FMNP voucher and CVV redemption); use of credible and relatable role models (i.e., WIC participants) and feedback to foster observational learning and outcome expectations; and education, experiential activities (e.g., web-mediated skills-building exercises) and delivery modalities that engage and sustain learners' interest to build knowledge and skills [37–40]. Culture-centric approaches to health promotion program development emphasize the use of narratives or stories to facilitate behavior change [36, 37]. Narratives among audience members about experiences with a focal issue may ground programs so that they are more culturally meaningful [36]. Moreover, behavior change can be enhanced when stories address behavior-change issues and the lesson communicated in the story promotes health behavior change [37].

The Transportation-Imagery Model attributes narrative persuasion to “transportation,” becoming highly absorbed with a story. Transportation makes the story seem more like actual experience; transported individuals are less likely to counter-argue and to believe story propositions and to adopt the beliefs of characters with whom they identify [41, 42].

Development

Lesson development was informed by a community-based participatory research approach actively involving key stakeholders, i.e., state and local WIC agency representatives and WIC participants, as full partners in all phases of the work [43, 44].

WIC advisory board

At the start of the project, an advisory board of WIC agency administrators and staff was convened to meet monthly throughout the project. The board assisted with the development of the lesson and is providing ongoing direction on the coordination of study activities. Monthly meetings document materials reviewed by the board and corresponding recommendations; problems, if any, encountered and strategies to avoid or resolve them; and timeline adherence.

Focus groups

Four focus groups per module (two in English and two in Spanish) were planned to gather feedback specific to the different modules. In total, 14 groups were held, as additional feedback was sought regarding one of the modules. Trained bilingual (English-Spanish) RAs moderated the groups. Groups consisted of 4–5 participants each ($N=56$ participants total) and were 50 min in length. To obtain in-depth information from participants, three questions per group were asked (the questions differed for each module), affording each participant 3 min to respond to each question. Groups of questions (and corresponding modules) were focused on attributes of WIC participants featured in the lesson, settings in which shown, and events serving as catalysts for behavior change (Farm Fresh); perceived rewards of eating FVs, reasons to eat locally grown seasonal items, and focal FVs [participants sorted picture cards depicting locally grown seasonal items into piles of familiar and unfamiliar items and selected one item in each pile that they would like to learn more about] (Market Smarts); and reactions to a 4-min FV food safety video (what was liked and what, if anything, might be difficult to do) [45] and FV recipes (In the Kitchen). The groups were tape-recorded. Audiotapes were transcribed and analyzed using tape-based analysis [46]. Findings guided the development of a written curriculum of lesson content.

The written curriculum guided the development of storyboards for each module. Using established guidelines [47], a second round of 12 focus groups was held ($N=52$ participants) to gather feedback on 1) likely effects of the module on targeted knowledge, attitudes and skills, 2) content, if any, that should be eliminated, and 3) content, if any, that should be changed to increase potential effects. Data were analyzed using the same approach as that used to analyze data from the first set of groups [46]. The written curriculum was revised based on the feedback.

Video production

Advisory board members identified English- and Spanish-speaking WIC participants to narrate lesson modules based on character attributes identified in the first round of focus groups. Videos were filmed on location in settings identified by the groups. WIC participants agreeing to narrate the modules received \$50 gift cards (redeemable at local supermarkets and chain stores) for each half-day of filming. English- and Spanish-language storyboards developed for the second round of focus groups served as video scripts. RAs assisted the narrators in rehearsing the scripts.

Pretesting video segments

Participant reactions to “rough cuts” of video segments developed for the first lesson module were assessed in one-on-one sessions with RAs using the think aloud method [48]. Five participants each viewed English- and Spanish-language versions of the segments. Following a brief rehearsal of the response task, the participant pre-viewed the focal video and verbalized reactions to it. After the video, participants were orally administered brief measures of the extent of identification with the narrator and transportation into and liking of the video (Cronbach alphas $\geq .76$) [42, 49, 50]. Probes were used to explore reasons for answers given. The feedback guided edits to and/or re-filming of footage lacking quality, relevance and impact. The revised segments underwent pretesting in a second round of 1:1 sessions. Lessons learned from pretesting the segments served as a guide for filming the remaining lesson modules.

Website development

Developed in HTML, the lesson consists of a user interface with audio output, video segments, Adobe Flash activities, content managed pages (with information on local farmers’ markets for WIC administrators to edit as needed), and reporting tools (reports by WIC participant identifier of lesson modules completed). Internal testing by RAs documented the absence, if any, of required features. The documentation served as a guide for the multimedia producer to revise, beta-test, debug and finalize the lesson in preparation for the outcome study.

Measures

Although measures of adult FV-related knowledge, attitudes and skills exist, measures of farmers' market-specific constructs are lacking and were therefore developed. Adapted from existing instruments (Cronbach alphas $\geq .70$) [40, 51–59], up to ten items per scale were written (some negatively worded to avoid a response set) [60]. Response options are on a yes-no, true-false, multiple choice or 7-point Likert scale format tailored to the nature of the questions. Cognitive testing with 15 participants gathered data for improving items and response formats that were unclear and/or difficult to understand [61]. The psychometric properties of the measures will be examined using data from the full administration of the instruments at pretest.

At pretest, the following sociodemographic variables are measured: date of birth, age (in years), pregnancy status, due date (pregnant women), breastfeeding status, race, ethnicity, nativity, preferred language, language(s) spoken at home, marital status, educational attainment, educational attainment of spouse or partner, number of children in the household under age 19, number of children in the household between 2 and 5 years of age, number of other adults in the household, employment status, participation in assistance programs and food security status. Because self-reports of FV intake are influenced by social approval and social desirability biases [62, 63], social desirability trait is also assessed at pretest using a validated, short form of the Marlowe-Crowne Social Desirability Scale [64].

Assessed at pretest, posttest and 3- and 6-month follow-up, outcome measures are knowledge of the FMNP and WIC-authorized farmers' markets, attitudes towards farmers' market FVs, awareness of locally grown, seasonal FVs, farmers' market FV purchases (ever purchased FVs at a farmers' market, purchased FVs at a farmers' market in the past 2 weeks), intentions to purchase FVs at a farmers' market in the next 2 weeks, FV food safety skills, farmers' market asking and FV preparation skills, and positive outcome expectations for consuming locally grown FVs (measured using instruments developed for the study). The frequency and quantity of FV intake are assessed with validated instruments [65, 66]. Frequency of intake is measured using the FV module of the Behavioral Risk Factor Surveillance System, shown to have moderate validity and reliability [65, 67]. Quantity of intake is measured with a 2-item screener developed by the National Cancer Institute [66]. The screener is valid (as evidenced by moderate correlations with FV intake assessed via multiple 24-h dietary recalls) and reliable (as evidenced by moderate 2–3 week test-retest correlations) [66]. FMNP voucher and CVV farmers' market FV purchases are assessed using voucher redemption data provided by the state WIC agency.

Process measures include lesson dose (data recorded by RAs and tracked through the website on the number of lesson modules and activities participants completed [a total of three each for those completing the lesson and one each for those completing existing online health education]), distractions, if any, experienced during lesson play (recorded by RAs), participant self-report data on existing online lessons, if any, completed prior to the study, user satisfaction with the lesson received (ratings, on a 7-point scale, of the extent of enjoyment, interest in, and likelihood of recommending the lesson to other WIC participants), measures of new information learned from the lesson and talking to family and friends about new information learned [49], whether this was the first time completing an online WIC nutrition education lesson and the perceived novelty of the lesson [49]. Among women who receive the lesson, measures of the following also are administered: what was remembered most about the lesson [49]; what was liked and disliked about the lesson and what, if anything, could be done to improve it; transportation into the video narrative [50] and identification with the characters [42]; liking and learning from lesson activities; the activity that was liked the most; the FV the participant chose to learn a recipe about and whether the participant tried the recipe at home; and whether the participant opened follow-up emails sent after the lesson, watched the videos, and tried the recipes shown and the perceived helpfulness of the information provided. Among all participants, RAs collect information on the number screened, determined eligible/ineligible and enrolled/not enrolled (during recruitment), and follow-up calls made/completed, follow-up assessments scheduled/completed and problems, if any, encountered in reaching participants.

Data collection

All self-report data are collected by RAs in 1:1 interviews with participants (interviews are conducted in person at pretest and by telephone at posttest and follow-up measurements). One month prior to 3- and 6-month follow-up assessments, RAs telephone participants to confirm their contact information and the date/time of their follow-up interview (participants are also mailed the date/time of their appointment 1 month and 2 weeks prior to the appointment). To enhance the quality of measurement, RAs were trained in a full-day session prior to data collection. Daily half-hour debriefing sessions are used to discuss problems, if any, encountered with data collection, ways to address them and strategies to avoid their recurrence.

Data analyses

To verify the success of randomization, between-arm differences in sociodemographic variables and prior

lessons received will be examined using analysis of variance or chi-square tests as appropriate. Characteristics of women who completed the study and those lost to attrition also will be compared. Variables found to differ by arm will be included as covariates in outcome analyses. Outcome variable distributions will be assessed and normalizing transformations applied as needed. If the transformations are unsuccessful, analyses will be implemented as generalized linear models with the appropriate error distributions (e.g., Gamma or Poisson).

Outcome analyses

Using an intent-to-treat approach (i.e., all women analyzed as randomized regardless of their adherence to the protocol), analysis of covariance (ANCOVA) models will be used to test hypotheses 1–3. The models will relate posttest FV intake to pretest FV intake, study arm, and covariates identified in preliminary analyses (described above). Tests of pair-wise differences in least-square (LS) means specified in hypotheses 1–3 will determine support for each hypothesis. In a parallel fashion, lesson effects on the redemption of CVVs at farmers' markets and on FMNP voucher redemption (among women who received the vouchers [hypotheses 4–5]) will be examined. Next, hypotheses 1–5 will be tested in a longitudinal context using linear mixed-effects (LME) models with three repeated measures. Tests of pair-wise differences between LS means specified in hypotheses 1–5 will determine whether lesson effects are sustained over time.

Mediation analyses

The method of Baron and Kenny and MacKinnon [68, 69] will be used to determine evidence for mediation by knowledge, attitudes and skills (hypothesized mediators) of lesson effects on FV intake and voucher redemption (hypothesis 6). Both single- and multiple-mediator models will be tested. Using ANCOVA for posttest measurements and LME for longitudinal follow-up, lesson effects on potential mediators will be examined. Significant lesson effects that are reduced when controlling for potential mediators (evaluated using Sobel tests) [70, 71], will provide evidence that partial mediation has occurred; the percent of variation in outcomes mediated by knowledge, attitudes and skills will be determined [72]. The absence of lesson effects after controlling for the mediators will indicate that complete mediation has occurred.

Dose-response effects

Positing that receipt of more of the lesson (as measured by the number of completed modules and activities) will foster more positive outcomes, hypothesis 7 tests dose-response relationships. This hypothesis will be examined in a series of ANCOVA and LME models (using data

provided by women who received the lesson) with posttest and follow-up measures of FV intake, voucher redemption, knowledge, attitudes and skills as outcomes, lesson dose as the fixed factor, and receipt of FMNP vouchers, socio-demographic variables and pretest measures of each outcome as covariates. The significance of the coefficient for the lesson dose variable will determine support for hypothesis 7. Similarly, for those who received existing online health education, the significance of the variable reflecting which of the lessons was received will be evaluated.

User satisfaction

Descriptive statistics will examine satisfaction ratings among women who received the lesson. A mean item score ≥ 5.0 (on the 7-point scale) will be considered evidence of a high degree of satisfaction. In a test of hypothesis 8, mean satisfaction ratings will be compared to determine whether satisfaction was higher among women who received the lesson relative to those who received existing online health education. Responses to open-ended items will be summarized. The feedback will be used to identify areas for further refining the lesson.

Expected outcomes

Previous work demonstrates that FMNP effects are stronger when vouchers are supplemented with nutrition education [18]. In light of this work, it is anticipated that at posttest and follow-up measurements, the highest levels of intake will be found among women who receive the lesson and FMNP vouchers (relative to women who receive the vouchers and existing online health education and those who do not receive FMNP vouchers and receive the lesson or existing online health education). Regardless of which lesson women receive, at posttest and follow-up measurements, FV intake is expected to be higher among those who receive FMNP vouchers relative to those who do not, owing to research demonstrating that by improving economic access to FVs, the provision of vouchers leads to improvements in FV intake [13–16]. Regardless of FMNP voucher receipt, FV intake and redemption of CVVs at farmers' markets also are expected to be higher among women who receive the lesson relative to those who receive existing online health education, owing to improvements in targeted knowledge, attitudes and skills. Improvements in these outcomes also are expected to result in higher voucher redemption among voucher recipients who receive the lesson relative to those who receive existing online health education.

In tests of secondary study hypotheses, it is expected that the lesson will promote positive changes in targeted knowledge, attitudes and skills and that these improvements, in turn, will lead to increases in FV intake,

FMNP voucher redemption and the redemption of CVVs at farmers' markets. Further, it is expected that receipt of more of the lesson will be associated with more favorable changes in targeted knowledge, attitudes and skills. Finally, it is anticipated that user satisfaction will be uniformly high among women who receive the lesson and will be higher in this group as compared to women who receive existing online health education owing to features of the lesson intended to capture and sustain users' interest, i.e., delivery through a highly accessible medium, the narrative lesson format, use of credible and relatable role models to deliver key messages and inclusion of interactive elements and activities.

Discussion

The present investigation addresses low FV intake, an issue of public health concern, among WIC participants, a population at increased risk of inadequate intake, and leverages vouchers provided by WIC to improve FV access in this population. Developed through a research partnership with New Jersey state and local WIC agency representatives, the lesson was designed to fit within WIC clinic operations, fully engage WIC participants in the development and delivery of lesson content, and modify behavior using a cost neutral approach (one allowing WIC to continue to offer the lesson at no or minimal costs after the study concludes; costs are modest and encompass fees to host the online lesson). The intervention adds to the limited number of theory-driven, web-based nutrition education lessons expressly designed for WIC to promote farmers' market FV purchases and consumption. If effective, the lesson has the potential to exert a powerful and sustained economic and behavioral impact. Methodological strengths of the study include the randomized design, use of an active control group, validated measures of both the frequency and quantity of FV intake, objective measures of FMNP voucher and CVV redemption, and repeated measurements, which will permit examination of the sustainability of lesson effects over time. Through planned dissemination efforts, the lesson will reach other WIC participants similar to those engaged in the research. Although the study sample and location limit transferability to diverse WIC audiences in other parts of the country, the lesson may nevertheless serve as a model for the development of similar resources tailored to local needs.

Abbreviations

ANCOVA: Analysis of covariance; CW: Cash value voucher; FMNP: Farmers' market nutrition program; FV: Fruit and vegetable; LS: Least square; LME: Linear mixed effects; RA: Research assistant; WIC: Special Supplemental Nutrition Program for Women, Infants and Children.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

JD, principal investigator of the study, and DM, co-investigator, conceived of the study and participated in its design and coordination. KWC provided methodological guidance on the design and implementation of the study. AS assisted with the sample size determination, provided statistical guidance and will assist with statistical analyses. All authors contributed to drafting and revising the manuscript and approved the final manuscript.

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