


Developing a Diet and Physical Activity Intervention for Hispanic/Latina Breast Cancer Survivors

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Abstract

Objectives: There is limited guidance on how to effectively educate cancer survivors to adopt and maintain specific diet and physical activity recommendations, especially among underserved and under-resourced populations. Here, the objective is to present the development of a behavioral and theoretically-based multi-modal diet and physical activity intervention program for Hispanic/Latina breast cancer survivors, *Mi Vida Saludable* (My Healthy Life).

Methods: The development process was based on the 6 steps of the Nutrition Education DESIGN Procedure: (1). **D**ecide behaviors; (2). **E**xplore determinants; (3). **S**elect theory-based model; (4). **I**ndicate objectives; (5). **G**enerate plans; and (6). **N**ail down evaluation. The theoretical framework for the intervention is Social Cognitive Theory.

Results: The resulting behavioral intervention consists of 2 components. The first component is in-person group education consisting of 4 lessons over 1 month. Each 4-hour group lesson includes a hands-on cooking component, a physical activity component, and facilitator-led nutrition education and discussion, with 2 field trips to a local grocery store and farmers' market. The second component is an e-Health program that includes weekly text messages, biweekly emailed newsletters, and ongoing website access.

Conclusion: The systematic DESIGN Procedure provided practical guidance for developing a behaviorally-focused, theory-based, and culturally sensitive program that addresses both dietary and physical activity behaviors for delivery both in-person education and through eHealth. The Procedure may be useful for developing other behaviorally focused and theory-based interventions.

Keywords

diet, nutrition, physical activity, breast cancer, Hispanic/Latina, curriculum

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Introduction

Breast cancer is the most commonly diagnosed cancer among women and is the most common cancer among Latinas.¹ While Latinas have lower incidence of breast cancer than woman who are non-Hispanic white, they are more likely to be diagnosed with invasive breast cancer at a younger age and at an advanced stage, and are more likely to die younger than non-Hispanic white women.^{2,3} These disparities may be due to a number of factors, such as lack of access to medical services and high chronic disease comorbidities, such as diabetes and obesity.

Lifestyle behaviors, including certain dietary patterns (eg, low fruit and vegetable intake, high intake of energy-dense foods) and physical inactivity, are risk factors for breast cancer recurrence.⁴ The American Institute for Cancer Research (AICR) states that more than 30% of breast cancer recurrences and deaths are preventable by post-diagnosis lifestyle modifications. AICR and American Cancer Society (ACS) recommendations for cancer survivors include eating a diet high in fruits/vegetables and low in fat and added sugar, and engaging in regular physical activity.^{4,5} Despite these recommendations, most cancer survivors, including breast cancer survivors, do not meet these guidelines.^{6,7} Studies have shown that intake of F/V and diet quality can vary across Hispanic subgroups,⁸⁻¹⁰ as Latina breast cancer survivors include populations stemming from multiple cultural and national backgrounds.¹¹⁻¹³ Our prior work has shown low fruit/vegetable intake and low physical activity in Latina breast cancer survivors living in Northern Manhattan.^{14,15}

Simply providing recommendations for improving diet and activity behavior is not sufficient to change and maintain these behaviors long term.^{16,17} Effective nutrition and physical activity education to support behavior change requires effective motivation and facilitation, including providing environmental supports.^{16,18-22} Nevertheless, after a breast cancer diagnosis, current clinical practice is typically a brief nutrition consultation with a registered dietitian and/or the provision of educational pamphlets and/or digital materials on diet and nutrition. The availability of nutritional counseling services for breast cancer patients varies across cancer centers and are not reimbursed by many insurance plans.²³ Few culturally-tailored resources and programs exist for Hispanic/Latina populations to improve diet and physical activity, particularly in the Spanish language.

Nutrition and physical activity education programs are more effective if they are systematically developed and administered, behaviorally-focused, theory-based, and culturally tailored.²⁴⁻²⁶ Moreover, these programs are more effective if they are logistically feasible and tailored for a specific population based on their needs.^{5,25,26} Intervention frameworks, such as RE-AIM,²⁷ PRECEDE-PROCEED,²⁸ the Behavior Change Wheel,²⁹ Intervention Mapping³⁰ translate research into practice and are useful for community-based interventions that incorporate individual, educational, environmental

and ecological levels of factors. However, these frameworks do not provide practical guidance on the development of specific health education program curricula, group sessions, and materials. The Nutrition Education DESIGN Procedure (DESIGN) was developed to fill this gap.¹⁶ It is unique in that it provides a detailed procedure for designing group *direct* education (eg, lesson plans for group sessions) and *indirect* education (eg, handouts, newsletters, recipes, email, online venues) aimed at individual-level behaviors and determinants of change. DESIGN stands for: (1). *Decide behaviors*; (2). *Explore determinants*; (3). *Select theory-based model*; (4). *Indicate objectives*; (5). *Generate plans*; and (6). *Nail down evaluation*. These steps guide the development of a specific intervention and tailor the intervention to the intended audience. DESIGN was developed for nutrition education and this is the first application to also include physical activity education. DESIGN uses *nutrition and exercise science* to determine the behaviors to address and content to include, *psychology* to determine the theory-based determinants, *educational theory* to sequence activities, and *communication theory* for effective implementation. Multiple behavioral interventions have recently been used in Hispanic/Latina populations.³¹⁻³³ Theory-based interventions to increase physical activity have also been described.³⁴ Literature reviews and recommendations for what to include in culturally sensitive interventions have been made.³⁵ However, descriptions of the use of specific structured frameworks involving systematic procedures with theory-based determinants of behavior change driving intervention development for this population have not been found. Using a structured framework in a cultural context provides the opportunity to develop more targeted, and therefore potentially more effective, curricula and materials.

DESIGN was used to create *¡Cocinar Para Su Salud!* (Cook for Your Health), a culturally-tailored curriculum for Hispanic/Latina breast cancer survivors, which we previously tested in a randomized, controlled trial to examine its effect on increasing fruit and vegetable intake and reducing dietary fat over 6 months.^{15,36,37} The intervention was based on Social Cognitive Theory³⁸ and the Transtheoretical Model.³⁹ Activities and education material targeted increasing self-efficacy and behavioral capability with observational learning and reinforcement through supportive group education and hands-on skills building lessons. Compared to the control group, participants in the 9-session program increased fruit and vegetable intake at 3 and 6 months, and also at 12 months (+2 servings/day) ($P < .05$ at all timepoints); both groups decreased dietary fat intake at 6 months with no differences between groups. Key determinants of behavior change were self-efficacy and change in taste preferences.⁴⁰ Participant feedback and class attendance logs suggested reducing the length of the intervention to improve retention and adherence. In addition, with the rise in the use of electronic media among the Latinx population comparable to the general population,⁴¹ we hypothesized that future nutrition education through such

media may address barriers such as time constraints and scheduling conflicts.

This article describes the use of the systematic DESIGN Procedure¹⁶ to modify the nine-session culturally-tailored *¡Cocinar Para Su Salud!* curriculum into a program called *Mi Vida Saludable* (My Healthy Life) with 2 intervention components: direct group education and electronic health (e-Health) communication. The intended audience is Hispanic/Latina breast cancer survivors living in Northern Manhattan and the program was designed to be tested in a National Cancer Institute (NCI) funded 2x2 factorial-designed randomized controlled trial with 4 arms: group education alone, e-Health alone, group education plus e-Health, and control (with the control arm participants receiving all study materials at the end of their participation).¹¹ *Mi Vida Saludable* had the same dietary behavior change goals as *¡Cocinar Para Su Salud!* which were to increase fruits and vegetables and to decrease foods with excessive fat and sugar. *Mi Vida Saludable* also added the behavior change goal to increase physical activity.

The group education component of *Mi Vida Saludable* consisted of 4-hour sessions. Each session included hands-on cooking, physical activity, and facilitator-led nutrition and physical activity education and discussion. Two sessions had field trips, one to a local grocery store and one to a farmers' market. The number of sessions was reduced from *¡Cocinar Para Su Salud!* to determine if fewer sessions could have the same behavior change impacts, as fewer sessions could improve retention and adherence, and facilitate wider implementation.

The e-Health component had the same behavior change goals as the group education component. It used the same psychosocial theory (described in more detail below) and was implemented through text messages, emailed newsletters, and access to a website over 11 months. The goal of testing this intervention component was to determine if this would result in similar behavior change as the in-person group sessions as this could address barriers such as intervention delivery costs, time constraints, and scheduling conflicts, and facilitate broader dissemination.

Description of the program design process for a behavioral research intervention can be useful to guide the development of future behavior-focused, theory-driven, and culturally-tailored group and e-Health education diet and physical activity interventions in breast cancer survivors and other populations.

Methods

Participants

Eligibility criteria for the intended population were self-identified Latinas age 21 years or older with a history of stage 0 to III breast cancer who were ≥ 90 days beyond surgery, chemotherapy, and radiation therapy (current use of

endocrine therapy allowed) without evidence of recurrent/metastatic disease. Women were Spanish- or English-speaking, lived in the New York area, and had low intake of daily fruits/vegetables (<5 servings per day) and/or low levels of weekly moderate-to-vigorous physical activity (<150 minutes per week). Women needed to have the ability to receive newsletters, email and/or text messages via computer, smartphone, or cellphone. Technology literacy was not required. From the outset, the research team was aware that the population of Latina breast cancer survivors living in Northern Manhattan is highly diverse in terms of national background, socioeconomic status, and level of acculturation.^{15,42,43} The intervention was designed to be broadly applicable to this population. Written, informed consent was obtained for participants who engaged in the pilot testing (n = 19). All procedures were approved by the Columbia University Institutional Review Board.

Development Team

The team developing the intervention included public health researchers, education researchers, community health educators, and members of community organizations involved in the delivery of nutrition and culinary education to cancer survivors. The team included research staff and community health educators reflective of the local population, including team members of Dominican, Mexican, Puerto Rican, Colombian, and Peruvian national backgrounds.

Results

Step 1: Decide Behaviors

Step 1 identifies the behaviors to address via the behavioral intervention targeting an underlying health issue. A thorough needs assessment of the intended population and a review of the literature and government and professional association recommendations determine the behavior change goal(s) for an intervention.

For *Mi Vida Saludable*, the behaviors to address were based on the AICR and ACS lifestyle recommendations for cancer survivors derived from extensive evidence⁵ and our previous work in the same intended population.³⁷ The specific behavior change goals were: (1) increase daily fruit and vegetable intake, (2) decrease percentage of daily calories from dietary fat, (3) decrease percentage of daily calories from added sugar, and (4) increase daily minutes of moderate to vigorous physical activity. Dietary behaviors were operationalized (Table 1) as increasing or decreasing specific foods frequently consumed by Latinas living in northern Manhattan.¹⁵ Our previous work in this population identified specific foods and drinks to target using multiple methods. Twenty-4 hour dietary recalls and interviews identified specific food eaten, including fruits and vegetables and high-fat culinary practices. Team members conducted neighborhood observations by physically

walking through the community, shopping at supermarkets and corner stores, eating at restaurants, and actively observing the social setting and behaviors while taking detailed notes of the availability and quality of healthy food options and the physical arrangement of products, offers, and pricing.^{15,36} (See Table 1) Specific physical activities to engage in were identified based on data from similar patient populations and focused on those that could be easily carried out independently in an urban setting.⁴⁴

Step 2: Explore Determinants

Step 2 identifies a list of potential determinants (or mediators) of behavior change that could be modifiable influencers of behavior change for the specific behavior change goal(s) and population, including *outcome expectations*, *perceived barriers*, *self-efficacy*, *preferences*, *behavioral capabilities*, *social support*, and *action goal setting*. Potential determinants are considered as contributors to *motivating* or *facilitating* behavior change. *Motivating determinants* provide inspiration and incentives for behavior change and are typically addressed early in the intervention to raise awareness of risks of the current behavior and benefits of change. *Facilitating determinants* help people believe they are capable of initiating a behavior change and are typically addressed in an intervention after participants have been motivated to develop specific skills to make behavioral changes. Potential determinants are explored with the population through methods such as interviews, focus groups and/or questionnaires to help select the appropriate psychosocial theory in Step 3.

Table 2 outlines target determinants in the *Mi Vida Saludable* program based on a literature review^{22,40,45-47} and our research team's prior work with this patient population that involved extensive assessments through key informant interviews, focus groups, and questionnaires, described elsewhere^{11,36} as well as our intervention-related experience with Latina breast cancer survivors in northern Manhattan over the course of several years.^{15,40,45,46}

Outcome expectations are physical, social, and/or self-evaluative beliefs about negative outcomes of current behaviors and about positive outcomes or benefits from performing the behavior change goal.⁴⁸ Theory-based determinants, including positive outcome expectations (perceived benefits), have been shown to contribute to meaningful changes in diet and physical activity.⁴⁶ Thus, in the intervention participants are presented with the benefits of eating more fruits and vegetables and less fat and sugar and increased physical activity to decrease recurrent cancer risk.

Perceived barriers are beliefs about challenges or costs of taking action, and *self-efficacy* is the level of confidence to successfully carry out the intended behavior.⁴⁸ Perceived barriers and self-efficacy are often paired because people increase their confidence in their ability to make behavior changes as they overcome behavior-specific barriers. In the intended population, perceived barriers include family

responsibilities and time constraints; preference for "familiar" vegetables and ways of cooking; and the commonly found low-cost "meat packages," often supplemented with "free" sodas, in their neighborhood stores.⁴⁹ To overcome common barriers, during the intervention, participants brainstorm ways to overcome barriers and learn quick and easy healthy cooking methods, how to create culturally-relevant meals, how to access culturally appropriate healthy options at local grocery stores, and how to engage in physical activities that can be done at home and in their neighborhoods. Self-efficacy is increased by being provided appropriate food and nutrition knowledge and guided practice in the targeted behaviors. The *¡Cocinar Para Su Salud!* intervention, using such activities, increased participants' confidence in making healthier dietary choices, and led to increased fruit and vegetable intake up to 12 months,^{15,40} similar to findings in other diet and physical activity interventions.^{45,46,50}

Preferences are personal inclinations towards specific foods or physical activities, which can be modified by repeated exposures to new tastes, foods, and activities.¹⁶ Taste or food preferences have predicted dietary fat intake among breast cancer patients and survivors.⁵¹ The *¡Cocinar Para Su Salud!* trial found that taste preferences for fruit and vegetables mediated increased intake.⁴⁰ Consequently, this intervention focused on providing opportunities to try new culturally-relevant foods and modes of physical activity so they could identify and choose those that they enjoy.

Behavioral capabilities refer to the food and nutrition- and physical activity-related knowledge and cognitive and behavioral skills that participants can use to modify their behaviors and maintain the changes in their lives going forward. Thus, the intervention provides participants with knowledge about the AICR/ACS recommendations for diet and physical activity, which foods are low in fat and added sugar, proper portion sizes of foods high in fat and added sugar, and appropriate types and amounts of physical activity. Cognitive skills include estimation of portion sizes of fruits and vegetables and the amount fat in foods and sugar in drinks. Behavioral skills included preparing foods that follow AICR/ACS recommendations learned through demonstrations followed by hands-on skill-building cooking activities with feedback, enhancing food shopping skills through visits to a supermarket and farmers' market, and increasing physical activity by learning how to use the wearable physical activity tracker given to all participants.

Social support and *action goal setting* have both been shown to predict physical activity and dietary behavior.^{45,52} *Social support* includes emotional, instrumental, information, and appraisal support provided by individuals in social networks to each other. Social support and social networks have been shown to be important in Latino populations^{53,54} and in similar Latina breast cancer survivor populations with whom we have worked.⁵⁵ Social support is incorporated here by creating a safe and supportive group environment^{56,57} and by participants cooperatively cooking together and eating the

Table 1. *Mi Vida Saludable* Targeted Behavior Change Goals.

Behavior change goals	Target	Focused behaviors
Increase physical activity	30 minutes 5 days per week of moderate to vigorous physical activity	Choose more physical activity Choose more leisure time physical activity Choose more physical activity while traveling Choose less sitting/sedentary activity
Increase fruit and vegetable intake	5 or more servings of fruits & vegetables per day	Choose more non-starchy vegetables, leafy greens, cruciferous vegetables (excluding juices, potatoes, fried vegetables, legumes)
Decrease intake of energy dense foods	Decrease total dietary fat and saturated fat intake	Choose animal protein low in fat (chicken without skin; lean ground meat; Turkey or chicken deli slices; Turkey or veggie burgers; meat with visible fat trimmed) Choose dairy products low in fat (less cheese; low-fat or fat-free milks and yogurts) Use less fat in cooking (oil instead of butter and lard; smaller, measured amounts of any type of fat while cooking; baked and broiled fish; baked potatoes and plantains)
	Decrease total added sugar intake	Choose drinks with less added sugar (water, sparkling water, 1% or skim milk, unsweetened iced tea; coffee and tea without or low in added sugar) Choose processed foods low in added sugar (certain yogurts; salad dressings and sauces;0 cereals) Choose dessert foods low in added sugar (fresh, frozen, canned in its own juice, and baked fruit and plain yogurt)

Table 2. Objectives of *Mi Vida Saludable* Group Education and e-Health Components Mapped to Corresponding Determinants.

Determinant type	Potential determinants	General objectives
		Participants will be able to...
Motivating determinants	Outcome expectations: Negative (perceived threat)	Evaluate their own behavior compared to recommendations and understand the risk of their current behaviors
	Outcome expectations: Positive (perceived Benefits)	Demonstrate understanding of importance of engaging in target behaviors
	Perceived barriers Preferences	Identify barriers to engaging in target behaviors Demonstrate appreciation of different types and tastes of target foods and activities
Facilitating determinants	Social supports0	Demonstrate increased awareness of social support of engaging in target behaviors
	Behavioral capability (nutrition- and physical activity-related knowledge and skills)	Identify strategies to meet diet and physical activity recommendations; demonstrate increased skills in food preparation and physical activity that follow AICR/ACS recommendations
	Self-efficacy Goal intention/Action goal setting	Demonstrate increased confidence to engage in target behaviors State intention/action goal to improve target behaviors

meal they have cooked. *Goal intention* and *action goal setting* create specific, measurable, attainable, realistic, and time-sensitive goals (ie, SMART goals) in order to achieve behavioral goals.¹⁶ Systematic reviews have found goal-setting, along with attendant self-monitoring, to be one of the most effective components associated with increased physical activity and improved diets.^{22,47,58} Consequently in this program, participants are taught goal setting skills for specific

behaviors or actions and are provided with action planning forms to facilitate the process.

Step 3: Select Theory-based Model

The purpose of Step 3 is to choose a behavior change theory or theories in order to provide a guide for selecting the specific motivating and facilitating determinants to address the

targeted behavior changes. These theories are based on research evidence and are applied depending on specific group demographics, group dynamics, and target behaviors.

In the *Mi Vida Saludable* program, the determinants identified in Step 2 align with Social Cognitive Theory, which posits that behavior is influenced by personal, social, and environmental factors.²⁰ Recent randomized controlled trials testing dietary and physical activity change in breast cancer survivors broadly use Social Cognitive Theory, with some resulting improvements in fruit and vegetable intake and physical activity.^{31,33,46} These trials report some description of the educational materials, but have not reported the process by which the curricula were developed. Our previous research in this population¹⁵ found that most of the woman were in the preparation and action stages of change making the Trans Theoretical Model, which focuses on moving participants through the stages, less relevant. Thus, Social Cognitive Theory was selected as the theory-based model (Figure 1).

Step 4: Indicate Objectives

In Step 4, general objectives are specified for each determinant in the theory-based model. General educational objectives are created based on the desired outcome of each determinant. Educational objectives guide the development of the educational plans and activities to support the intended audience in achieving the behavior change goal.

Table 2 outlines the general educational objectives for each determinant in the theory-based model of the *Mi Vida Saludable* program. These objectives guide the development of content and intervention materials. Educational objectives (“objectives” for short) are learner-based and begin with “Participants will be able to...” followed by an action verb (bolded below). For *outcome expectations: negative (perceived threat)*, the objective was to **evaluate** their own

behavior compared to recommendations and understand the risk of their current behaviors. For *outcome expectations: positive (perceived benefits)*, the objective was to **demonstrate** understanding of the importance of engaging in target behaviors. For *perceived barriers*, the objective was to **identify** barriers to target behaviors. For *preferences*, the objective was to **demonstrate** appreciation of different types and tastes of target foods and activities. For *social supports*, the objective was to **demonstrate** increased awareness of social support of engaging in target behaviors. For *behavioral capabilities*, the objective was to **identify** strategies to meet recommendations and to **demonstrate** skills in cooking dishes that follow AICR/ACS recommendations. For *self-efficacy*, the objective was to **demonstrate** increased confidence to engage in target behaviors. Finally, for *goal intention*, the objective was to **state** intention to improve target behaviors.

Step 5: Generate Plans

The purpose of this step is to create ready-to-use educational plans for group sessions. It starts with the development of a planning matrix that lists each theory-based determinant, along with its attendant behavior change *strategies*¹⁶ (also called behavior change *techniques*²⁴ or *methods*³⁰), specific educational objectives, and short descriptions of activities sequenced according to educational design principles.⁵⁹ This structure ensures that the educational plans systematically create purposeful, and likely more effective, activities that are sequenced according to their theoretical structures for effective delivery. Each educational plan follows 4 sequential phases, denoted as “The Four Es”: first *Excite* audiences to understand why the behavior change goal is important, then *Explain* the benefits of the behavior change goal and how to overcome potential barriers, then *Expand* by practicing and

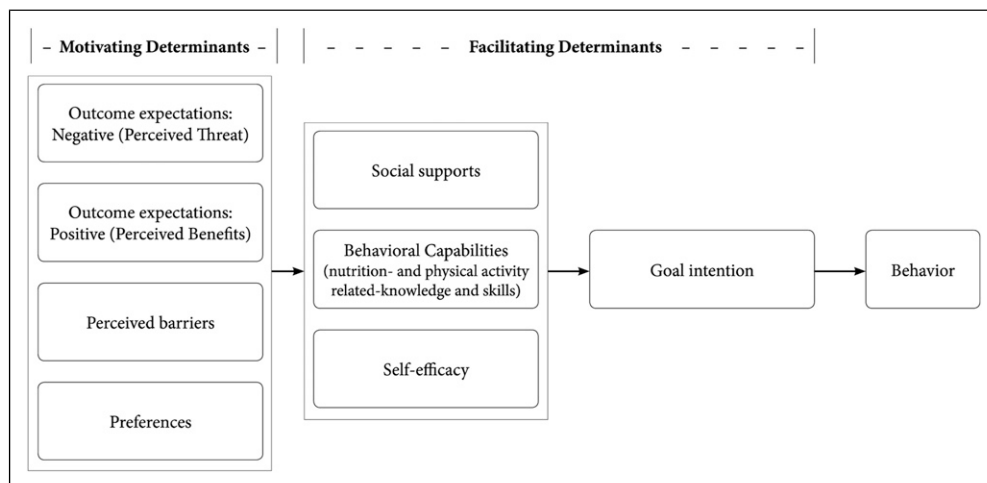


Figure 1. Modified social cognitive theory for *Mi Vida Saludable*. This figure illustrates the relationship between the proposed motivating determinants and facilitating determinants that result in behavior change as theorized in this intervention. Note: This model is based on Bandura 2004.²⁰

planning how to take action, and finally *Exit* by creating a clear action goal or plan to achieve the behavior change goal.

The *Mi Vida Saludable* program created educational plans for the group education component that incorporated interactive group education and hand-on skills building activities adapted from *¡Cocinar Para Su Salud!* and for the newly created e-Health education component.

The first task was to create a planning matrix listing each theory-based determinant (from Step 3) along with a behavior change *strategy* for that determinant. Next, a specific educational objective was written for each determinant. Next, for each component (group education and e-Health) the activities to address the determinant are briefly described. The plans for the group education and e-Health components are described in more detail below.

For the group education component, the activities for each determinant are sequenced according to educational design principles. This structure ensures that the educational plans are sequenced for effective delivery, and follows “The Four E’s” described above. These activities are hands-on cooking, experiential physical activity, discussions about creating action plans for the behavior change goal, and 2 field trips to a local grocery store and farmers’ market.

For the e-Health component, the activities for each determinant included a series of text messages that contained links to newsletters and the bilingual Cook for Your Life website. The text messages were sequenced to address the theory-based motivating and facilitating determinants for each behavior change goal in the same order used in the group education component. The text messages were sent out according to a planned schedule over 11 months. Articles in the newsletters addressed the behavioral determinants, and the Cook for Your Life website provided informational support also addressing the theory-based determinants.

Group Education. The *Mi Vida Saludable* group education component consists of 4 sessions, 4 hours each, implemented over a 1-month period. Table 3 presents the planning matrix for session 1, listing the *determinants* for eating more fruits and vegetables and fewer high-fat and high-sugar foods and for getting more physical activity, the behavior change *strategies (techniques/methods)* that operationalize the determinants, and the *specific objectives* that guide the creation of relevant *activities*. See the Supplementary Tables for the planning matrices for sessions 2, 3, and 4. The actual educational plans were generated from these planning matrices.

The first 2 sessions focus on motivating participants to understand and engage in the 4 behavior change goals, while the second 2 sessions focus on facilitating and helping participants engage in adopting the new dietary and physical activity behaviors. All sessions address both motivating and facilitating action determinants, with the first 2 sessions emphasizing motivating determinants and the final 2 sessions emphasizing facilitating action determinants.

Each session begins with an introduction and review of outcome expectations associated with the target behaviors. For sessions 2 through 4, action goals made by each participant at the end of the previous session are discussed to encourage support and revision of action goals as appropriate. Each group session includes both nutrition and physical activity education content, experiential skill building of physical activity behaviors, and culinary and nutrition skill building. Each session emphasizes a different type of physical activity to discuss and experience how more activity can easily be included throughout the day. The culinary and nutrition segments focus on different behavior change goals. The first session emphasizes motivational determinants for decreasing fat and added sugar, the second increasing fruit and vegetable intake, and the third and fourth sessions focus on facilitating determinants for all 3 diet behavior change goals. Sessions 1 and 2 teach main concepts in the classroom. Sessions 3 and 4 include tours of a local affordable grocery store and a farmers’ market. The last segment of each session involves culinary education, where women cook culturally relevant recipes. After cooking, the women eat a meal together to facilitate support and confidence in skills. Sessions conclude with women brainstorming ways to troubleshoot barriers to completing the target behaviors. Women complete action goal-setting worksheets for each target behavior.

e-Health. The *Mi Vida Saludable* e-Health component includes text messages, a bilingual cooking emailed newsletters, website for cancer survivors (cookforyourlife.org), and Fitbits for physical activity self-monitoring implemented over 11 months. Participants receive 2-5 text messages per week and 2 emailed newsletters per month. During the first half of the intervention period, 2/3 of the text messages address motivational determinants and 1/3 address facilitating determinants. In the second half of the intervention period this is reversed and 1/3 of the text messages address motivational determinants and 2/3 address facilitating determinants. Examples of how the text messages implement the specific theory-based determinants are shown in Table 4.

Results from text message-based lifestyle interventions have shown that best practice is to provide more text messages at the beginning of the intervention then decrease the text message frequency.⁶⁰ Thus, the number of text messages slowly decreases from 5 to 2 messages a week over the 11-month period. Text and email messages are bidirectional, allowing study staff to respond to participants.

The text message content parallels the group education content. Half of the text messages focus on diet (ie, increasing fruit and vegetable intake, and decreasing fat and added sugar intake) and half focus on physical activity (ie, increasing minutes of weekly physical activity). Once a month, text messages prompt women to set action goals, half related to diet and half related to physical activity. The women to respond to a goal setting question (eg, “Make a goal: How often do you think you can choose a low-fat meat such as 90-95%

lean ground meat or chicken without the skin this week? Text back your response: 1 = 1 time per week, 2 = 2 to 3 times per week, 3 = almost every day, 4 = every day.”) 1 week after these action goal-setting messages are sent, another message asks for feedback (eg, “Remember, last week we asked you to set a goal to eat less fat from meat or chicken this past week? How many times did you do it? Text back your response. 1 = 1 time this week, 2 = 2 to 3 times this week, 3 = almost every day, 4 = every day.”) This interactive approach encourages engagement and self-monitoring, which can lead to more sustained behavior change.⁶¹

E-newsletters are delivered via links embedded in text and email and are stored on a secure location on the bilingual Cook for Your Life website only accessible to study participants (www.cookforyourlife.org). (At the initiation of the research period, Cook for Your Life was a non-profit organization that provides nutrition education and cooking classes to cancer survivors in New York City; it has since closed and the Cook for Your Life website is now run out of the Fred Hutchinson Cancer Center.) Half of the newsletters’ content target diet and half target physical activity, with colorful and topical content aligning with the topic of the week and the behavior change being targeted. Each newsletter begins with a welcoming introduction from a member of the study staff and includes motivating and facilitating nutrition or physical activity information. In addition to newsletters, other links sent via text messages include links to Cook for Your Life recipes, dance videos from the local non-profit Moving for Life™ (movingforlife.org), and New York City government sponsored events promoting physical activity.

Pilot study of program before final curriculum completion. The group education program followed by a shortened version of the e-Health program was piloted with a small sample of breast cancer survivors (n = 19) for user testing and to receive participant feedback on the intervention. Changes to the materials were made based upon feedback received. After the pilot study was completed, a formative evaluation of the intervention was conducted. On a scale of 1 to 5 where 5 indicates greatest satisfaction, participants were very satisfied with both group education and eHealth portions of the intervention (range of mean responses was 4.8 – 5.0 for group education and 4.0 – 4.8 for e-Health). Major changes to the group education component included the addition of evidence-based information on common questions about fad diets. Logistical changes focused on field trip transportation to and from the grocery store and farmers’ market, and when and where meal and snack preparation should take place for each session.

Translation. Of note, this intervention was designed to be conducted in both Spanish and English, which meant that all materials needed to be available in both languages. A bilingual, multi-cultural, and multi-disciplinary team was assembled, including one certified translator, to translate the written

patient-facing materials (print and digital) and curriculum into Spanish and to review the translation for accuracy. Multiple sessions were used to refine and edit the translations to make sure that meaning was not lost in the translation process. As it was known in advance that the majority of the intended population would be Spanish-speaking, the in-person sessions were designed to be delivered by the health educators in Spanish with simultaneous live translation in English offered to participants who preferred to listen/participate in English. Participants opting for delivery in English listened with headsets while the onsite certified live translator provided translations. This arrangement allowed for participants and staff to request any translation clarifications as needed.

Step 6: Nail Down Evaluation Plan for the Education Program

This final step is to create the evaluation plan. Designing the evaluation plan at the same time as the intervention ensures appropriate methods are used to measure changes in the behavioral determinants and changes in the specific behavior change goal(s). Measuring changes in both determinants and behaviors can help elucidate mechanisms of behavior change and provide guidance on designing future interventions.

For *Mi Vida Saludable*, an evaluation plan was created to test the effectiveness in a 2x2 factorial-designed randomized controlled trial (RCT). Data are collected on the primary diet and physical activity outcomes at baseline, 6-, and 12-months. Dietary intake is assessed using 2 to 3 24-hour recall assessments using the multiple pass approach using the Nutrition Data System for Research (NDSR) developed by the Nutrition Coordinating Center at the University of Minnesota. Physical activity is assessed using the 7-day physical activity recall (7DPAR).⁶² A questionnaire to measure changes in Social Cognitive Theory behavioral determinants was developed and validated (Koch et al, manuscript in submission). The evaluation results will identify the most important determinants of diet and physical activity change for this population, which will have implications for future research and practice.

Discussion

The *Mi Vida Saludable* intervention consists of a four-session, 1-month nutrition and physical activity group education component and an 11-month e-Health component focused on improving diet and physical activity in Hispanic/Latina breast cancer survivors. Both components were created using the 6-step DESIGN Procedure. The Social Cognitive Theory based intervention targets 4 key behaviors: (1) increase daily fruit and vegetable intake, (2) decrease percentage of daily calories from dietary fat, (3) decrease percentage of daily calories from added sugar, and (4) increase daily minutes of moderate to vigorous physical activity. While DESIGN has previously

Table 3. Planning Matrix of Session I of *Mi Vida Saludable* Group Education Component.

Instructional theory step	Determinants	Behavior change strategy	Specific objectives	
			Participants will be able to...	Activity
Excite	Introduction 30 minutes <i>Overview of Mi Vida Saludable program</i> <i>Overview of AICR/ACS guidelines</i> Modes of education: PowerPoint presentation; group discussions			
	Social support	Provide social support	Describe class context as a supportive environment	Introduce all group members and instructors to create supportive group environments
	Outcome expectations (positive): Perceived benefits	Provide information about positive outcomes of target behavior	Demonstrate increased knowledge of benefits of following AICR/ACS recommendations	Give PowerPoint presentation and discuss information about benefits of making the target behavior changes
	Outcome expectations (negative): Perceived Threat/Risks	Provide information about negative outcomes of not performing target behavior	Evaluate personal risk of negative outcomes of not performing target behaviors	Give PowerPoint presentation and discuss striking statistics and other information about personal risk of negative outcomes of not performing target behaviors
Explain	Physical activity education 35 minutes <i>Lesson 1 Focus: Increasing physical activity at home</i> Modes of education: PowerPoint presentation; dance breaks; group discussions			
	Outcome expectations (positive): Perceived benefits	Provide information about positive outcomes of target behavior	Demonstrate increased knowledge of benefits of following AICR/ACS recommendations	Give PowerPoint presentation and discuss beneficial information of being more physically active
	Self-efficacy	Provide guided practice	View the behavior as easy to understand and complete	Assist individuals to achieve success by demonstrating behavior and providing practice by completing “dance breaks”
Explain	Dietary behaviors education 45 minutes <i>Lesson 1 Focus: Decrease dietary fat & added sugar intake</i> Modes of education: PowerPoint presentation; group discussions; worksheets			
	Outcome expectations (positive): Perceived benefits	Provide information about positive outcomes of target behavior	Demonstrate increased knowledge of benefits of following AICR/ACS recommendations for lowering fat and sugar intake	Give PowerPoint presentation and discuss information about benefits of eating a diet low in fat and added sugar
	Outcome expectations (negative): Perceived threat/Risks	Provide information about negative outcomes of not performing target behavior	Evaluate personal risk of negative outcomes of eating foods high in fat and added sugar	Provide striking statistics and other information about personal risk of negative outcomes of eating foods high in fat and added sugar
	Behavioral capability	Provide factual knowledge related to behavior	Develop an understanding of identifying foods low in fat and added sugar and proper portion sizes of foods high in fat and added sugar	Provide factual information related to eating foods low in fat and added sugar involving remembering and understanding, using lectures, visuals, slides, and handouts

(continued)

Table 3. (continued)

Instructional theory step	Determinants	Behavior change strategy	Specific objectives		
			Participants will be able to...	Activity	
Expand	Cooking 90 minutes <i>Lesson 1 Focus: Cooking methods and recipes to decrease dietary fat and added sugar intake</i> Modes of education: Cooking demonstration and guided practice	Behavioral capability	Provide active mastery experiences/guided practice	Cook foods with lower fat and added sugar	Demonstrate food preparation/cooking skills followed by guided practice with feedback through hands-on activities to develop cooking skills
	Self-efficacy	Provide guided practice	View the behavior as easy to understand and complete	Assist individuals to achieve success by providing clear instructions, demonstrating behavior, providing practice or direct experience	
Expand	Action goal setting 10 minutes <i>Lesson 1: Create increasing physical activity action goals</i> Modes of education: Worksheets	Perceived barriers	Prompt identification of perceived barriers	Identify barriers	Group brainstorms barriers to behavior change goals and ways to overcome barriers
	Goal intention/ Action goal setting	Stimulate action goal setting	State goal intentions and create action goals	Teach goal setting skills for specific behaviors or actions, provide action planning forms	
Exit	Communal meal 20 minutes	Taste preferences	Provide direct experience with healthful food	Consume foods low in fat and added sugar	As a group, consume meal low in fat and added sugar
	Social support	Enhance skills in management of social context	Evaluate class context as a supportive environment	Create supportive group environments eating together	

been used in other settings,⁶³ this is the first study that we are aware of to develop and test a theory-based educational program with similar content for both in-person group education and e-Health formats and for both diet and physical activity. This is also one of the first studies to use, and describe in detail, a systematic curriculum development process to develop such a program for a racial/ethnic minority population with a specific health concern.

The systematic DESIGN approach to curriculum development is unique in that while several other systematic procedures provide frameworks for translating behavioral theory into practice,^{29,64} they not to provide specific practical guidance on the next necessary step of how exactly to create educational behavior change activities and sequence them appropriately for individual sessions or for indirect venues such as electronic media. DESIGN fills this need by using effective instructional design theory from the field of education, accompanied by communication principles, to

structure and sequence activities into actual ready-to-deliver educational plans. The novel DESIGN planning matrix shown in Table 3 in particular helps with this process. It provides a clear delineation of how determinants of behavior change derived from a clearly stated theory drive the development of activities through the selection of appropriate behavior change strategies (or techniques or methods), and the writing of specific educational objectives. The matrix also shows how given sessions are sequenced according to education principles.⁵⁹ This study shows that DESIGN can be used for planning sessions addressing both diet and physical activity behaviors.

e-Health approaches to intervention have become widely used. They are generally based on tailoring content to individuals based on psychosocial, psychographic, and related variables.^{60,65} This study adds to the literature on the use of e-Health by showing how to use a systematic design procedure to facilitate the creation of e-Health text messages and

Table 4. Examples of Text Messages That Address the Theory-Based Determinants of Behavior Change.

Determinant	Text messages		
	Increase fruit & vegetable intake	Decrease dietary fat & added sugar intake	Increase physical activity
Outcome expectations of current behavior (negative): perceived risk	Eating lots of fruits and vegetables can decrease the risk of developing heart disease and diabetes	Think about how often you eat high fat meats like beef, pork, and sausage. It may be a lot! eating less is a healthier choice	Sitting for long periods of time can become boring, and is not good for your health. Try to get up every 30 minutes and move
Outcome expectations for targeted behavior (positive): perceived benefits	Eating more fruits and vegetables gives you more fiber and can make you feel fuller	Learn how choosing low fat is good for your health and find a tasty marinated chicken recipe in Mi vida Saludable news (also in your email!) Link14	Being physically active can help you be happier, healthier, and sleep better. Every step counts!
Perceived barriers	Fruit promotes healthy bowel function. Try dried or frozen fruit if fresh isn't available!	There are many Spanish speaking vendors at farmers' markets who can help you select foods and with EBT.	Going to the gym is expensive. There are many free and low cost active events in our NYC parks
Preferences	Try this delicious gelato recipe made with real fruit that's naturally low fat! Link28	Chicken can still taste great when it's made without the skin!	Try dancing to music or taking a walk with a friend
Self-efficacy	Stock up on frozen vegetables - they don't go bad. They're easy to add to your meals	There are easy ways to make your meals look like the new, beautiful, healthy "MyPlate"	Even though physical activity may be tiring at first, regular physical activity actually makes you feel energized!
Social support	Tell your family and friends about your goals to eat more fruits and vegetables. They can be great sources of support!	Ask your family to try new recipes with you - cooking together brings us together!	For a fun activity together, ask a friend or family member to take walks with you around the block, to the store, or to the park
Goal intention/action goal setting	Aim to eat all 5 colors - red, orange, yellow/white, green, blue/purple - to get all of the benefits each day!	Start your day the healthy way with a breakfast low in fat and added sugar	Set a goal for being more active at home - walk while on the phone, dance to videos, or dance while you clean
Behavioral capability – knowledge and cognitive skills	One serving of fruits and vegetables is about the size of your fist. Get at least 5 "fists" of fruits and vegetables each day for better health!	The size of your palm is a healthy portion of chicken, beef, and fish at a meal	There are guidelines for healthy eating and physical activity from national cancer organizations to improve overall health
Behavioral capability – behavioral	Kale is a leafy vegetable similar to spinach. It's easy to cook! Steam, sauté, or have in a salad!	If you eat red meat, try to eat it less often, choose cuts with less marbling, and cut off visible white fat before cooking	Housework counts as physical activity – sweep, wash, and tidy with energy!
	There is a lot of fat in French fries, fried plantains, fried yucca, and potato chips. Try this recipe for baked "fries" – you'll love the taste! Link25	Be aware of how much oil you use when you cook. Only use a little! use 1 teaspoon per person about the size of your thumb tip	Try taking the stairs instead of the elevator - even part of the way. Every step counts

e-newsletters based on a theory-based model and education principles to be delivered as a *structured program* addressing both dietary and physical activity behaviors. In addition, the schedule of delivery of text messages used educational theory principles, in particular sequencing the motivational messages early in the intervention and facilitating messages later in the intervention.^{59,66} E-Health approaches may be particularly beneficial as they have the potential to overcome the problem of time constraints and scheduling conflicts and may be more

scalable than in-person interventions.³⁹ The only e-Health nutrition and physical activity intervention for Latina breast cancer survivors identified to date was based on a smartphone app used by participants over a 6-week period along with 3 telecoaching calls based on motivational interviewing.^{67,68} The content of the app was primarily straightforward instruction on managing symptoms, medications, emotions, family, and friends. The study described here shows that the DESIGN procedure can be used to develop theory-based

education through both remote e-Health and in-person group sessions.

There are potential benefits to use of the DESIGN Procedure. The literature has shown that behavioral interventions are more effective if they are behaviorally-focused, theory-based, and directly address the determinants in the theory.^{16,26} Further, as diet and physical activity behaviors are complex, DESIGN allows program developers to create a theory-based model specific to a certain behavior for the audience. In addition, DESIGN calls for creating evaluation methods that specifically measure changes in behaviors and psychosocial theory determinants targeted by the intervention. The *Mi Vida Saludable* curriculum within each session and over the 4 sessions moves from motivating behavior change to facilitating decisions on new nutrition and physical activity behaviors. A distinction of the *Mi Vida Saludable* program is the cultural integration of the local Latina breast cancer survivor population from conception to execution of the intervention, following behavior change theory, both via in-person group education and e-Health communication.

Translating theory-based determinants into educational objectives, and then identifying evidence-based behavior change strategies and activities, allows researchers to develop similar programs across demographic groups and across various behavior change goals, and to compare outcomes consistently across populations.^{16,66} The methods by which behavior change curricula for cancer survivor populations are developed have rarely been described in detail, which prevents researchers from systematically building upon prior work. Culturally based and adapted programs are important for effectiveness and recommendations have been made for features to consider in developing such programs.^{25,35,69,70} The description of a *systematic procedure* to provide guidance for developing culturally-tailored or culturally specific *educational programs* for racial/ethnic minority populations has not been found, and there are limited education resources for Hispanic/Latina groups.

This description of the development of *Mi Vida Saludable* makes several contributions. First, *Mi Vida Saludable* provides guidance for developing future behavior change interventions with cancer survivors. Second, *Mi Vida Saludable* provides an example of an intervention that is culturally sensitive to ensure Hispanic/Latina women feel connected in terms of language and community, which has been shown as a strong desire among this group.⁷¹ Third, *Mi Vida Saludable* demonstrates how to develop complementary interventions using different mediums (ie, electronic and classroom based that address the same behavior change goals and theory-based determinants). In particular, the use of theory-based determinants of behavior change to guide the development of e-Health content and sequencing can inform future technology-delivered intervention programs targeting lifestyle behaviors among Latina breast cancer survivors. Practitioners designing brief interventions can use an abbreviated version of the DESIGN Procedure.¹⁶

Despite these strengths and contributions, there are potential limitations to this approach. To maximize generalizability, the intervention was designed for any Latina breast cancer survivor with non-metastatic disease post-diagnosis and post-treatment. If women are more likely to make changes based on stage at diagnosis or time since diagnosis, this intervention was not designed to address this. In addition, at the time this intervention was developed, there was little data upon which to base the frequency and content of the text messaging intervention⁶⁰; one of our goals was to use the methods and data generated from this research to help fill this gap.

When behavioral interventions are developed without describing their developmental process, replication and identification of effective strategies to address theory-based determinants are difficult. With a clear description using a systematic process, researchers and practitioners are able to conserve resources and move the field of behavior change forward more quickly and effectively. Further research can enhance the utility of the DESIGN procedure by investigating which components of the DESIGN Procedure are the most effective.

Conclusion

This detailed description of the development of MiVS shows how the systematic DESIGN Procedure can provide practical guidance for developing a behaviorally-focused, theory-based, and culturally sensitive program that addresses both dietary and physical activity behaviors. DESIGN creates a ready-to-deliver program by integrating *nutrition and exercise science* to determine the behaviors to address and content to include, *psychology* to select the theory-based model and determinants, *educational theory* to sequence activities, and *communication theory* for effective implementation. The DESIGN Procedure can be used to develop a program with similar behavior change goals, theory-based determinants, and content for both in-person group education and e-Health formats, thus permitting wide dissemination of a program. This procedure provides guidance for developing future behavior change interventions with persons who have survived cancer.

Abbreviations

ACS American Cancer Society

AICR American Institute for Cancer Research

DESIGN Decide behaviors, Explore determinants, Select theory-based model, Indicate objectives, Generate plans, and Nail down evaluation; NCI, National Cancer Institute

NDSR Nutrition Data System for Research

PRECEDE Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation

PROCEED Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development

RCT Randomized controlled trial
 RE-AIM Reach, Effectiveness, and Maintenance, and
 Adoption, Implementation, and Maintenance
 7DPAR Seven-day physical activity recall

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Ethical Approval

Ethical approval to report this case was obtained from the Columbia University Institutional Review Board (Protocol ID AAAP0461).

Statement of Human and Animal Rights

All procedures in this study were conducted in accordance with the Columbia University Institutional Review Board (Protocol ID AAAP0461) approved protocols.

Statement of Informed Consent

Written informed consent was obtained from the patient(s) for their anonymized information to be published in this article.

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Supplemental Material

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