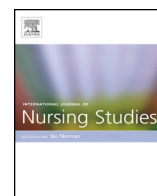




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A community health worker-led lifestyle behavior intervention for Latina (Hispanic) women: Feasibility and outcomes of a randomized controlled trial[☆]



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ABSTRACT

Background: Low-income Latinas (Hispanics) face risk for cardiovascular disease due to high rates of overweight/obesity, sedentary lifestyle, and other factors. Limited access to health care and language barriers may prevent delivery of health promotion messages. Targeted approaches, including the integration of community health workers, may be required to promote healthy lifestyle and prevent chronic disease in underserved ethnic minority groups. The term commonly used to refer to female community health workers in Latino communities is “promotora(s).”

Objectives: This study evaluates the outcomes and feasibility of a promotora-led lifestyle behavior intervention for overweight, immigrant Latinas.

Methods: A community prevention model was employed in planning and implementing this study. A randomized controlled trial design was used. A Community Advisory Board provided expertise in evaluating feasibility of study implementation in the community and other important guidance. The sample was comprised of 223 women aged 35–64 years, predominantly with low income and ≤8th grade education. The culturally tailored Lifestyle Behavior Intervention included group education (8 classes based upon Su Corazon, Su Vida), followed by 4 months of individual teaching and coaching (home visits and telephone calls). The control group received a comparable length educational program and follow-up contacts. Evaluations were conducted at baseline and at 6 and 9 months using a dietary habits questionnaire, accelerometer readings of physical activity, and clinical measures (body mass index, weight, waist circumference, blood pressure, lipids, blood glucose). Data were collected between January 2010 and August 2012.

Results: Women in the intervention group improved significantly in dietary habits, waist circumference, and physical activity in comparison to those in the control group. A treatment dosage effect was observed for weight and waist circumference. Knowledge about heart disease increased. High attendance at classes and participation in the individual teaching and counseling sessions and high retention rates support the feasibility and acceptability of the promotora-led lifestyle behavior intervention.

[☆] Trial Registration NCT01333241.

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Conclusions: Our findings demonstrate that lifestyle behaviors and other risk factors of overweight Latina women may be improved through a promotora-led lifestyle behavior intervention. Feasibility of implementing this intervention in community settings and engaging promotoras as facilitators is supported.

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What is already known about the topic?

- Latina/Hispanic women, particularly those of Mexican descent, face increased risk for cardiovascular disease (CVD) due to high rates of overweight/obesity and other risk factors.
- Interventions with a combined focus on heart-healthy dietary habits and physical activity may promote lifestyle behavior changes that decrease the prevalence of risk factors among Latinas.
- Most community-based studies that have evaluated lifestyle behavior interventions facilitated solely by community health workers (promotoras) with overweight/obese, immigrant Latinas have used nonexperimental designs.

What this paper adds

- Overweight/obese, immigrant Latinas receiving the Lifestyle Behavior Intervention in a nonclinical, community setting demonstrated significant improvements in dietary habits, waist circumference, and physical activity as well as significantly increased knowledge of heart disease compared to those in the control group.
- Findings of this randomized controlled trial support the feasibility and positive outcomes of implementing a promotora-facilitated Lifestyle Behavior Intervention in the community with overweight/obese Latinas.

1. Introduction

The influence of healthy lifestyle behaviors on cardiovascular disease risk reduction has long been recognized. Optimal behaviors include healthy dietary practices, a physically active lifestyle, no tobacco smoking or exposure to environmental smoke, and weight control (Pearson et al., 2013). Despite widespread information about these modifiable lifestyle behaviors, risk factors for cardiovascular disease and other chronic diseases continue to be higher among ethnic/racial minority populations in the United States, who also may face other socio-environmental risks. In particular, persons who self-identify as Hispanic or Latino, reflecting origins in the countries of Central or Latin America, face risk for cardiovascular disease and diabetes. (Note: Hispanic and Latino are often used interchangeably; however, in this paper usage is based upon distinctions made in published reports). The prevalence of overweight and obesity is disproportionately higher among Latinas than non-Hispanic white women (Office of Minority Health, 2005). Low-income Latinas, particularly those of Mexican descent, face increased risk for cardiovascular disease due to overweight/obesity,

sedentary lifestyle (Roger et al., 2012), and other risk factors such as type 2 diabetes, hypertension (Boykin et al., 2011), metabolic syndrome, and dyslipidemia (Ervin, 2009). Although the traditional diet of Latinos is healthy (e.g., high in legumes and fresh vegetables), as they become acculturated into the United States, they may adopt unhealthy dietary behaviors characterized by low nutritional quality, high caloric density, and high fat content (Neuhouser et al., 2004).

Interventions with a combined focus on heart-healthy dietary habits and physical activity may promote lifestyle changes that decrease the prevalence of risk factors among Latinas. Although many lifestyle behavior interventions and reviews of studies have been conducted, few include samples composed solely of Latinos; multi-ethnic subsamples are often combined in analyses of outcomes. Findings of a meta-analysis of psycho-behavioral obesity intervention trials among ethnically diverse adults in the United States support the benefits of multi-component programs and integrating individual sessions, family involvement, and problem solving strategies (Seo and Sa, 2008). The value of lifestyle interventions with dietary manipulation strategies and engagement in physical activity delivered over the long term for effective weight management is highlighted in other reviews that do not target programs among minority adults (Brown et al., 2009; Kirk et al., 2012; Shaw et al., 2005). Other benefits reported from exercise and/or dietary interventions, particularly those involving overweight/obese individuals and/or those with risk factors for type 2 diabetes, include very modest improvements in lipids, decreases in anthropometric measures and systolic and diastolic blood pressure levels (Orozco et al., 2008; Shaw et al., 2006), and healthier dietary behaviors (Eakin et al., 2007).

1.1. Background

Lifestyle behavior programs are commonly conducted with at-risk populations in community health centers and hospital clinics. The interventions are delivered by clinically trained professionals working alone or with specially trained community (lay) health workers. In Latino communities, community health workers are commonly known as *promotores* (feminine, *promotoras*). As part of the health care team, *promotores* provide information and emotional support. An example of this model of care is the clinic-based WISEWOMAN program in California, which involved community health workers alongside health professionals in lifestyle health promotion with low-income Latinas at risk for cardiovascular disease. Women receiving the intervention showed improvements in eating habits and physical activity,

systolic blood pressure, and 10-year cardiovascular disease risk assessment, but no significant change in body mass index or cholesterol levels (Hayashi et al., 2010). Other clinic-affiliated studies based on the WISEWOMAN program similarly support positive dietary and physical activity outcomes (Khare et al., 2012; Staten et al., 2004). A modest but significant weight reduction was reported for Latinos at risk for diabetes who participated in a lifestyle behavior intervention delivered by bilingual, bicultural community health workers (Ockene et al., 2012). The latter randomized controlled trial involved collaboration with a community health facility and senior center.

Limited experimental research has been conducted to evaluate lifestyle behavior interventions delivered solely by promotoras with non-clinical populations outside of community health centers and hospital clinics. Studies involving Hispanic communities in promotora-led lifestyle behavior interventions using the Your Heart, Your Life (*Su Corazón, Su Vida*) curriculum often employ pretest-posttest research designs to compare outcomes from baseline to postintervention (Balcázar et al., 2009; Staten et al., 2005, 2012). Positive outcomes have been reported in these non-experimental studies, including improvements in anthropometric measures (body mass index, weight, waist circumference) (Balcázar et al., 2009; Horowitz et al., 2011; Staten et al., 2012) and lipoprotein profiles (Balcázar et al., 2009; Staten et al., 2012), decreases in blood pressure (Balcázar et al., 2009; Staten et al., 2012), and increases in self-reported measures of physical activity (Staten et al., 2005). One of the few randomized community trials using promotores and involving Hispanic women with at least one identified cardiovascular risk factor was conducted by Balcázar et al. (2010). Findings showed that participants receiving the intervention (classes based on the *Su Corazón, Su Vida* curriculum) had more awareness of cardiovascular risk factors and confidence in the control of these factors, improved dietary habits, and more favorable lipoprotein (cholesterol) profiles compared to those in the control group. In another randomized controlled trial, Mexican-American women receiving a promotora-led physical activity intervention for coronary heart disease risk reduction experienced significant reductions in body mass index but no changes in anthropometric and blood lipid results between the baseline and 36-week measures (Keller and Cantue, 2008). Research findings also suggest that a higher dose of educational sessions by promotoras is associated with improved behavioral changes in self-reported dietary habits (Sánchez et al., 2014).

Systematic literature reviews of community health worker programs worldwide provide evidence of their effectiveness for certain behaviors and disease categories (Gibbons and Tyus, 2007; Lewin et al., 2005; Rhodes et al., 2007; Viswanathan et al., 2009; Wells et al., 2011). Integration of community health workers in community models of prevention is most appropriate and in accord with the American Heart Association's call for preventing the onset of disease and maintaining optimal cardiovascular health among broader segments of the population (Pearson et al., 2013). Factors influencing adoption of healthy lifestyle behaviors among underserved populations such as Hispanics also warrant consideration. Findings from a systematic

review reveal that engagement in physical activity among Hispanics may be improved by interventions incorporating cultural values and messages and involving staff from the same ethnic group such as community health workers (Ickes and Sharma, 2012). Family support for lifestyle changes has been associated with adoption of healthy behaviors among Hispanics (Kohlbray and Nies, 2010; Marquez and McAuley, 2006). Juarbe et al. (2002) report that Hispanic women have multiple role responsibilities that interfere with social interactions, including physical activity. Perceived neighborhood safety and access to facilities that enable physical activity to occur also are concerns expressed by Hispanics (López et al., 2008). Further, environmental influences on eating associated with obesity are more intensified in low-income communities where many Hispanics reside, such as a high prevalence of high calorie, low nutrient foods (Bowie et al., 2007; Calzada and Anderson-Worts, 2009; DeBono et al., 2012; Pérez-Escamilla, 2011). Other studies similarly report that Hispanic participants in promotora-led interventions encounter barriers to nutritious and affordable food and lack of recreational options (e.g., access to gyms) (Sánchez et al., 2014).

In summary, although a variety of studies and reviews support the benefits of lifestyle behavior interventions facilitated by community health workers, much of the evidence is based upon pre- and post-intervention comparisons of outcomes rather than scientifically rigorous clinical trials. In several studies community health workers are part of medical teams working in community or hospital clinics with identified at-risk populations, rather than delivering interventions independently in nonclinical settings (Hayashi et al., 2010; Khare et al., 2012; Ockene et al., 2012; Staten et al., 2004). The design of studies, differences in intervention components, and the exclusion of control groups often make it difficult to draw conclusions about the overall effectiveness of community-based interventions by promotoras. This study addresses the need for randomized clinical trials to enhance understanding about the effectiveness of lifestyle behavior interventions delivered exclusively by promotoras in community settings with underserved populations of Latina women.

A community prevention model was employed in planning and implementing this randomized controlled trial. Unlike many past investigations of lifestyle behavior programs, women were recruited from the general population of Latinas rather than based upon identified risk factors or affiliation with a clinical facility. The purpose of our study was to evaluate the effects of a lifestyle behavior intervention delivered by specially-trained promotoras to low-income, overweight, immigrant Latinas residing in Southern California. Outcomes were evaluated using measures for dietary habits, objective physical activity, and selected cardiometabolic indices. Acceptability and feasibility of the intervention were evaluated through examination of women's retention rates and participation in classes and home visits.

2. Materials and methods

A community-based participatory research conceptual framework was applied based upon recognition that

collaboration is a key strategy in effectively reducing health disparities in underserved communities. Work between the community and academic partners in planning and implementation of research was established over a decade ago, beginning with an assessment of population needs and context, subsequent pilot testing of research protocols, and involvement of promotoras and a Community Advisory Board (Kim et al., 2004, 2005). The Community Advisory Board, identified through recommendations of community key informants and composed of community stakeholders, service providers, local residents, and a member of the clergy, met regularly to provide guidance in study planning, implementation, and evaluation. Potential promotoras were also recommended by Community Advisory Board members. The conceptual underpinning of the study and ethical considerations required an alternative educational program of potential benefit to the community be offered as the control condition. The focus of both the experimental and control conditions, sample class schedules, and evaluation procedures were described within the informed consent so that participants would understand the two educational programs and related outcome measures. Research protocols were approved by the Institutional Review Board of the University of California, Los Angeles. Baseline assessments were done after securing written informed consent and before randomization, to minimize influence from group assignment. Randomization was performed using a web-based program custom-developed for this study. Participants were assigned to the Lifestyle Behavior Intervention or the control group in a 1:1 ratio using a block randomization procedure. Several strategies were employed to increase retention rates, including use of a case management approach to build rapport, telephone reminders for classes and evaluations, participant incentives (\$25 gift cards for each evaluation, bus tokens, small gifts for class attendance, and a health record of their weight, blood pressure, and lipids) and flexible scheduling. Child care was provided for each class. All group education sessions for both the experimental and control groups were conducted by separate teams of promotoras in community settings such as school classrooms.

2.1. Study population, recruitment, and participants

The study was conducted from January 2010 to August 2012 in two adjacent communities of Los Angeles with large populations of sociodemographically similar Latinas. Participants were recruited in four consecutive intervention cycles from parent education centers, churches, laundromats, and organizations providing basic services to children and families (e.g., English-as-a-Second-Language classes, job training, social services). Specially trained recruiters gave small group and individual presentations providing an overview of the study and program announcements.

After an overview of the study provided to small groups or individuals, women interested in enrolling were screened for eligibility. The inclusion criteria were: self-identified Latina, 35–64 years of age, Spanish- and/or English-speaking, and overweight (BMI ≥ 25). The age

range was determined with consideration of our desire to reach as many women as possible in this community prevention effort. Nonetheless, age limits were employed to optimize control factors and constrain individual variability to some extent. The lower age limit of 35 was used because Latinos have high risk factors for cardiovascular disease at early ages. Identified cardiovascular disease risk factors, such as pre-diabetes or hypertension, were not specified as eligibility requirements, as prevention was the primary focus of the intervention. The nature of the intervention and Internal Review Board considerations necessitated that those who self-reported a history of impaired physical mobility, type 1 diabetes, uncontrolled hypertension, heart attack, or stroke be excluded. A health clearance was required for those with type 2 diabetes or hypertension controlled by diet and/or oral medications.

2.2. Lifestyle Behavior Intervention (experimental condition)

The 6-month Lifestyle Behavior Intervention, referred to in the community as *Mujeres Sanas y Precavidas* (Healthy Women Prepared for Life), was comprised of group education plus Individual Teaching and Coaching. The first 2 months included 8 weekly classes based upon *Your Heart, Your Life* (*Su Corazón, Su Vida*), a culturally relevant, promotora-led educational program developed for Latino communities by the [National Heart, Lung and Blood Institute \(2008\)](#). The primary goal of this curriculum was to promote healthy lifestyle behaviors (diet and physical activity) for reduction of cardiovascular disease risk. During each 2-h class, held in community settings, promotoras worked in pairs to deliver the standardized content from the intervention manual. Ten minutes of each class were devoted to instructor-led stretching and exercising presented in a DVD produced by the Los Angeles County Department of Public Health. Individual sessions were available to make up missed group classes. After completion of this component, participants received Individual Teaching and Coaching from their promotora, designed to reinforce class content, assist them achieve personal goals, support behavior change, and provide guidance on how to overcome barriers to lifestyle behavior change. The Individual Teaching and Coaching included 8 contacts (4 home visits plus 4 telephone calls) delivered over 4 months. Coaching guidelines and a binder of visual displays were created with involvement of the promotoras. The Lifestyle Behavior Intervention was implemented in Spanish as preferred by participants.

Although our adaptation of *Su Corazón, Su Vida* emphasized strategies to promote weight loss, original content was retained, including information on heart functioning, heart attack symptoms, heart-healthy eating for Latino families, physical activity, cholesterol, living smoke free, diabetes, and hypertension. Participants learned how to plan, choose, and prepare heart healthy diets for traditional Latino meals (e.g., fruits, vegetables, low-fat or fat-free milk and milk products, lean meats, poultry and fish) and about serving sizes. A variety of approaches were applied to motivate behavioral changes; e.g., videos, role play (skits), and supplementary low-literacy, culturally appropriate

brochures published by the National Heart, Lung and Blood Institute were distributed. Participants established personal goals for lifestyle changes. Four key messages were emphasized: (1) healthy food choices, (2) portion control, (3) managing emotional eating, and (4) increasing physical activity, with the goal of walking 10,000 steps per day. To promote self-monitoring and physical activity, participants received an Accusplit Eagle pedometer and a copy of the exercise DVD used in class. Past research shows that the use of pedometers positively influences physical activity (Bravata et al., 2007). In addition, culturally-appropriate recipes and a “hunger scale” were given to participants. Use of food and physical activity diaries was encouraged to enhance self-awareness of lifestyle behaviors. The diaries were discussed with promotoras during Individual Teaching and Coaching sessions rather than collected for program evaluation.

2.2.1. Intervention adherence and promotora fidelity

Adherence was assessed using retention rates with data from class attendance sheets and recordings of Individual Teaching and Coaching contacts. Activities to foster and monitor program fidelity for promotoras included orientation to the study and extensive training in the curriculum and protocol-defined content, behavior change, and human subjects protection; regular staff meetings with opportunities to discuss experiences; and observations of performance in classes and home visits to verify both accuracy of content and appropriateness of counseling in the Individual Teaching and Coaching sessions. Tracking session and promotoras’ testimonials about their experiences have been used in other studies of *Su Corazón*, *Su Vida* as methods of determining integrity of program implementation (Balcázar et al., 2006; Sánchez et al., 2014).

The promotoras participated in approximately 100 h of structured training activities, including 4 days focusing on delivery of modules in *Su Corazón*, *Su Vida* (conducted by a bilingual promotora trainer with extensive experience implementing the curriculum and educating promotoras) and research-specific skill sessions. All promotoras had a high school diploma or equivalent, 4 or more years’ employment as a community health worker, and either resided in or had extensive work experience in the community where the study was implemented.

2.3. Control condition

A 6-month safety/disaster preparedness educational program was conducted by a separate team of promotoras, not involved in the intervention. Eight classes covered topics such as earthquake preparedness, preventing spread of influenza, home safety for children and elders, and managing home emergencies. Following this group education, Individual Teaching and Coaching was offered (8 contacts) that provided opportunity for more in-depth discussion about class content on disaster preparedness and home safety. Upon completion of the study, participants were offered two classes highlighting key information presented in sessions of *Su Corazón*, *Su Vida*.

2.4. Data collection and instruments

Data were collected at baseline, and at 6- and 9-month follow-ups. Questionnaires were administered via face-to-face interviews; a bilingual research assistant, blinded to participant’s group assignment, read the items and recorded the answers. Lipids and blood pressure assessments were performed by a registered nurse of Mexican descent.

2.4.1. Dietary habits

This 27-item measure assessed heart-healthy behaviors associated with salt and sodium consumption, cholesterol and fat intake, and weight control practices. Item responses are on a 4-point scale (0 = never to 3 = always). The questionnaire includes items that address healthy food choices, portion control, and emotional eating. Examples include “Choose fruits and vegetables instead of salty snacks like chips...”, “Drink 1% or skim milk”, “Eat more when feeling stressed” and “Eat smaller portions of food and do not go back for seconds.” The questionnaire, developed in Spanish as part of the National Heart, Lung and Blood Institute’s Initiative for Latino Cardiovascular Disease Prevention, underwent translation to English and was independently reviewed by a committee of bilingual translators to establish conceptual equivalence, content validity, and cultural appropriateness for varying groups of Latinos. Several *Su Corazón*, *Su Vida* studies report acceptable internal consistency (Balcázar et al., 2006, 2009; Medina et al., 2007). Internal consistency for this sample was satisfactory, with Cronbach’s $\alpha = .79$.

2.4.2. Physical activity

The Kenz Lifecorder Plus Accelerometer (Kenz, Nagoya, Japan) was used to measure physical activity. It assesses vertical acceleration and generates “counts” of movement highly correlated with steady-state oxygen consumption ($r = .88$) (Freedson et al., 1998). The Lifecorder activity counts were converted into METS (1 MET = 3.5 mL/kg min), thus enabling classification of intensity according to accepted standards as well as measurement of steps. Studies have established that this is a reliable and valid monitor for measuring physical activity (Furukawa et al., 2003; Niinomi et al., 1998; Schneider et al., 2003; Thompson et al., 2004). Participants were to wear the accelerometer during waking hours for 7 consecutive days at each physical activity data collection period. Both verbal and written instructions with illustrations were provided to ensure compliance. Review of the Lifecorder data revealed no evidence of manipulated recording due to device misuse (e.g., shaking).

2.4.3. Body weight, height, and waist circumference

Weight was measured using a digital scale (SECA 769) to the closest 0.2 lb., with women wearing light clothing and no shoes. Height was measured to the closest 0.1 cm using the SECA 220 Hite-Mobile Portable Stadiometer. Body mass index was calculated as kg/m². Waist circumference was evaluated using a Gulick tape measure following the National Obesity Expert Panel Report guidelines (National Heart, Lung and Blood Institute,

2000). The data collectors attended special training on performance of these skills that required establishing 95% agreement or higher between their readings and those of a professional nurse on 10 separate evaluations of weight, height, and waist measurement. During the course of the study, reliability was maintained for each measure by performance of consecutive evaluations by the data collector and project director on a random sample of 35 participants (test-retest reliability).

2.4.4. Blood pressure

Measurements of blood pressure were obtained applying procedural guidelines of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (Chobanian et al., 2003), using a Welch Allyn and Tycos Blood Pressure Kit with TR-2 ProCheck Home Aneroid and Stethoscope. This device meets the Association for the Advancement of Medical Instrumentation (AAMI) accuracy standard of 3 mmHg. Elevated blood pressure readings were rechecked using a mercury sphygmomanometer (average of 3 readings).

2.4.5. Blood lipids and glucose

Fasting blood samples were obtained in the early morning via a fingerstick. Levels of total serum cholesterol, HDL-C, LDL-C, triglycerides, and blood glucose were assessed using the Federal Drug Administration-approved Cholestech LDX lipid analyzer (Cholestech Corporation, Hayward, CA). The Cholestech is Clinical Laboratory Improvement Amendments (CLIA)-waived and meets National Cholesterol Education Program guidelines for precision and accuracy.

2.4.6. Knowledge of heart disease

A 10-item questionnaire, administered at the beginning and after the 8 weeks of classes, assessed knowledge of heart disease. Participants were asked to respond, using a true/false format, to statements such as “Heart disease is the leading cause of death in women,” and “Men and women experience the same symptoms of a heart attack.” Items also assessed prevention behaviors and awareness that early treatment exists. The questionnaire was adapted from one used in a national survey of women’s understanding of heart disease and prevention behaviors (Mosca et al., 2004). Reliability for this sample was acceptable ($\alpha = .80$).

2.4.7. Demographic questionnaire

A basic questionnaire assessed background variables, including age, marital status, place of birth, length of time in the United States, family income level, health history, and current report of feeling depressed. Acculturation was measured using a validated 5-item scale which evaluates primary language spoken, primary language read, childhood setting, ethnic background of friends, and pride in Latino background (Balcázar et al., 1995).

2.5. Analysis

Data were analyzed using SPSS Version 19. Average daily steps and average daily minutes of moderate-to-vigorous

physical activity were calculated from Lifecorder readings. To examine equivalence of groups on background and health characteristics at baseline and related need for adjusting for covariates, *t*-tests for continuous variables and chi-square analyses for categorical variables were conducted.

Group differences (between intervention and control) on outcome variables were assessed using mixed effects models for repeated measures over time (Hayat and Hedlin, 2012; Hedeker and Gibbons, 2006; Littell et al., 2006). This approach is conceptually similar to ANOVA, but allows the inclusion of the entire analysis sample, even if some participants had missing 6-month or 9-month follow-up observations (thus, a modified intent-to-treat analysis, rather than analysis of only the subsample with complete follow-up data). Because preliminary analyses showed that the intervention and control groups differed significantly by age, age was included as a covariate in the analysis of outcomes. Note that while groups also differed on baseline hypertension, both diastolic and systolic blood pressure were significantly related to age ($p < .002$); thus, the blood pressure measures were not included as additional covariates because of their redundancy with age. For each outcome measure, groups were compared to assess whether their patterns differed across the 6- and 9-month follow-up evaluations above any pre-existing baseline differences (that is, the “group-by-time interaction effect” in the mixed model described above). To further evaluate the timing of potential intervention effects, we also examined group differences in terms of their specific change from baseline to 6 months and from baseline to 9 months (using *t*-statistics from specialized contrasts within the mixed models). Systolic and diastolic blood pressure measures were treated separately for the outcome analyses.

To examine the treatment dosage (intensity) on main outcomes, intervention participants were classified into two categories (low/medium and high intensity levels) based upon class attendance and Individual Teaching and Coaching contacts received. Those attending at least 7 of the 8 classes and with at least 7 of the 8 additional contacts were considered high intensity; the remaining participants were categorized as low/medium. A mixed model, similar to that described above, was used to compare the two intensity subgroups (within the intervention group) to see if they differed in their patterns of change over time (the subgroup-by-time interaction effect), adjusting for age.

2.5.1. Power analysis

The sample size available for analysis was sufficient to allow detection of small-to-medium effects with power = .80 and 2-tailed alpha = .05, adjusting for attrition and assuming a moderate correlation over time in repeated measures analysis (Hedeker et al., 1999). More specifically, this detectable effect size (as described in the commonly used standardized metric “*d*”) was $d = .36$ for clinical outcomes, indicating that an approximate difference between groups of .36 of a standard deviation (for a specific outcome) by 9 months would be detectable after adjusting for covariates and attrition.

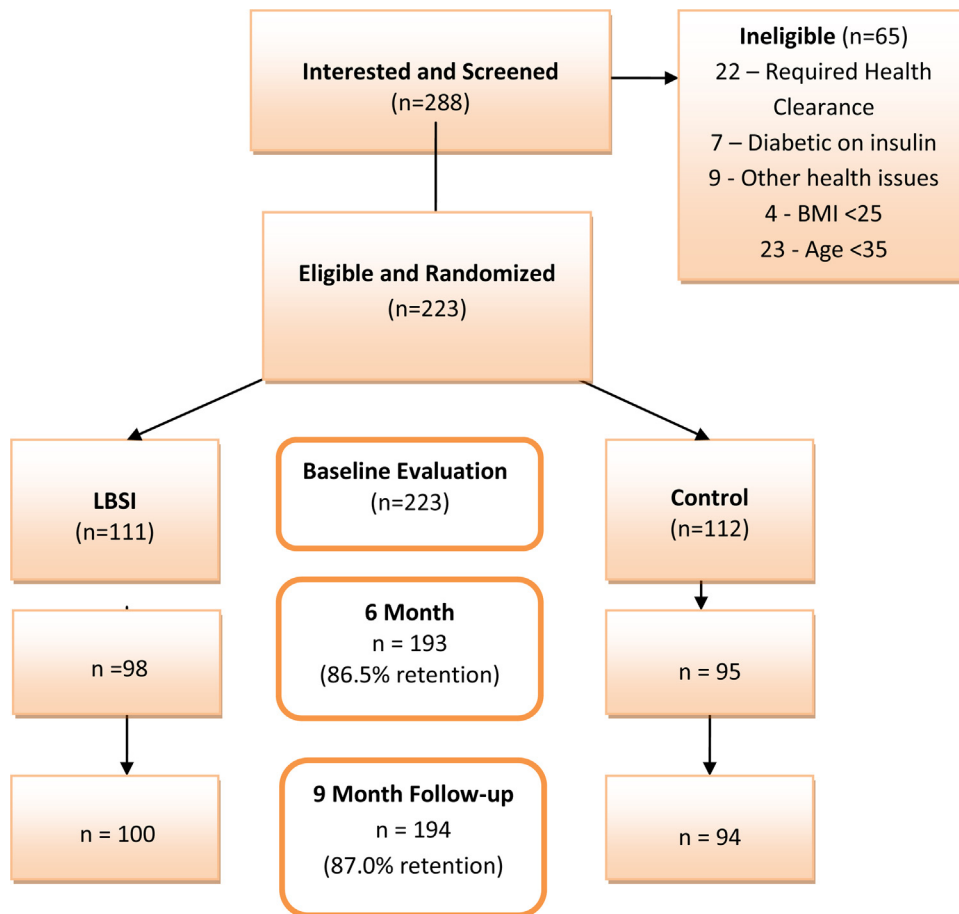


Fig. 1. Recruitment and retention flowchart. LBSI, lifestyle behavior intervention: control, disaster/home preparedness.

3. Results

3.1. Sample description

The eligibility screening and baseline data measures were administered to 288 and 223 participants, respectively (see Fig. 1); 65 were ineligible due to exclusion criteria or not securing a required health clearance. Of the enrolled women, 111 were randomly assigned to the Lifestyle Behavior Intervention and 112 to the control condition. Retention was 86.5% and 87.0% for the 6- and 9-month evaluations, respectively. The baseline characteristics of the women are displayed in Table 1. The sample was composed of predominantly low-income women, mean age 44.6 years; most (83.9%) were of Mexican descent. The education level was \leq 8th grade for 52.5%. Despite lengthy residence in the United States (mean 18.6 years), acculturation level was low, 1.5, and showed little variation. Diabetes and hypertension rates, based on our clinical data ($BP \geq 140/90$) or self-reported history, were 6.3% and 12.1%, respectively. Although 53% of the women did not report depressive symptoms in the past month, 25% stated they felt depressed (sad) or were often “bothered by loss of interest,” and 22% admitted to both of these emotions. Age, menopausal status, acculturation,

birthplace, education, depression symptoms, and other demographic variables were assessed for equivalence between groups at baseline, with no statistically significant differences found except for age and hypertension classification. Because of these baseline differences, as described in Section 2.5, age was included in the analysis as a covariate; but hypertension indicators were not included as covariates due to their strong correlation with age.

Thirteen participants were excluded from physical activity analyses because they did not meet the accelerometer recording criteria; i.e., a minimum of 4 days of data (≥ 8 h/day) as per commonly applied guidelines (Miller et al., 2013). Thus, analyses included $n = 223$ for most clinical outcomes and $n = 210$ for physical activity outcomes. Our analyses showed no difference in background variables between the women excluded from the physical activity analysis and the larger sample.

3.2. Acceptability and feasibility of intervention

Retention rates and intervention participation are two indicators of the acceptability and feasibility of the intervention. Overall retention rates for both groups at the 6- and 9-month follow-ups were high, 86.5% and 87%, respectively. The frequent contacts of promotoras with the

Table 1
Demographic characteristics of participants at baseline by intervention group.

	Lifestyle behavior intervention (n = 111)	Control (n = 112)	Total (N = 223)	t-Test/ χ^2 values	p
Mean age \pm SD	43.3 \pm 7.4	45.9 \pm 8.2	44.6 \pm 7.9	6.53	.01*
Age range (min-max)	35–63	35–64	35–64		
Mean acculturation level \pm SD ^a	1.4 \pm 0.4	1.5 \pm 0.5	1.5 \pm 0.5	1.99	.16
Acculturation range (min-max)	1.0–3.0	1.0–3.4	1.0–3.4		
Mean years living in US \pm SD ^b	17.7 \pm 8.3	19.5 \pm 8.1	18.6 \pm 8.3	2.71	.10
Year range (min-max)	1–37	1–40	1–40		
Birth Place, n (%)					
Mexico	92 (82.9)	95 (84.8)	187 (83.9)	2.38	.67
U.S. (but raised in Mexico)	3 (2.7)	1 (0.9)	4 (1.8)		
Other (Dominican, Central or South American)	16 (14.4)	16 (14.3)	32 (14.3)		
Language Spoken, n (%)					
Only Spanish	61 (55.0)	60 (53.6)	121 (54.3)	1.07	.78
Education, n (%) ^c				.99	.80
\leq 8th grade	57(51.4)	60 (53.6)	117 (52.5)		
9th–12th grade	37(33.3)	38 (33.9)	75 (33.6)		
\geq 13 years	16 (14.4)	12 (10.7)	28 (12.6)		
Marital status, n (%)				1.33	.25
Married/living with partner	84 (75.7)	77 (68.8)	161 (72.2)		
Divorced/widowed/single	27 (24.3)	35 (31.2)	62 (27.8)		
Income, n (%)				1.84	.40
\leq \$20,000	57 (51.4)	65 (58.0)	122 (54.7)		
\$20,001–\$40,000	32 (28.8)	32 (28.6)	64 (28.7)		
\$40,001–\$75,000	22 (19.8)	15 (13.4)	37 (16.6)		
Unemployed, n (%)	79 (71.8)	87 (77.7)	166 (74.8)	1.01	.32
No health insurance, n (%)	78 (70.3)	74 (66.1)	152 (68.2)	.46	.79
Health Problems, n (%)					
Diabetes (FBS \geq 126 mg/dL or on antidiabetic therapy)	6 (5.4)	8 (7.1)	14 (6.3)	.29	.59
Hypertension (BP \geq 140/90 mmHg or on BP meds)	7 (6.3)	20 (17.9)	27 (12.1)	6.99	.01*
Felt depressed (sad) and “bothered by loss of interest” in the past month	25 (22.5)	24 (21.4)	49 (22.0)	1.02	.60

^a Based on 1–5 questions with the rating scale: (1) only Spanish, (2) Spanish better than English, (3) both English and Spanish equally well, (4) English better than Spanish, (5) only English. Higher score means more acculturated.

^b Based on responses of 204 women; excludes 7 intervention and 4 control group women (4.9%) responding $>$ 25 years and 5 intervention and 3 control group women (3.6%) who did not know or refused to respond.

^c Based on responses of 220 women; excludes 1 intervention and 2 control group women (1.3%) who did not know or refused to respond.

t-Tests were used for continuous variables and chi-square tests were used for categorical variables.

* Significant group difference.

women facilitated high retention, as they knew when and where participants moved. The retention rates across groups were not statistically different (see Fig. 1). Participants who did not complete the 6- and 9-month evaluations were considered noncompleters. No statistically significant differences in demographic or clinical characteristics were found between completers and noncompleters.

Attendance data showed that of the 111 women in the intervention group, 42 (37.8%) attended all classes; 91 (82%) attended at least half; and 79 (71.2%) at least three-fourths. Participation in the follow-up Individual Teaching and Coaching was similarly high, with 86 women (77.5%) receiving the targeted number ($n=4$) of home visits. Only 6 women (5.4%) received none of the planned follow-up intervention. Thirty-one women (27.9%) received all components of the intervention. The high rate of attendance for classes and participation in the Individual Teaching and Coaching show that the intervention was well accepted by Latina women.

3.3. Behavioral outcomes

Intervention and control groups differed significantly in their pattern of dietary habits across the study period, controlling for age (group-by-time interaction from the mixed model $F[2,176]=4.87, p=.009$). Overall scores for dietary habits improved for women who received the intervention, suggesting an improvement in healthy eating behaviors in the intervention group but not in the control group. Intervention effects on dietary habits occurred by 6 months (differential change baseline to 6 months, $p<.01$) and continued (from baseline to 9-month follow-up, $p<.01$).

Measures of physical activity based on average daily steps are displayed in Fig. 2. At baseline women in both groups were fairly active, with mean daily step counts above 8500. The groups differed significantly (controlling for age) in their change from baseline to 9 months (contrast $t=2.07, df=201, p=.04$). More specifically, there was a statistically significant decrease in activity in the control

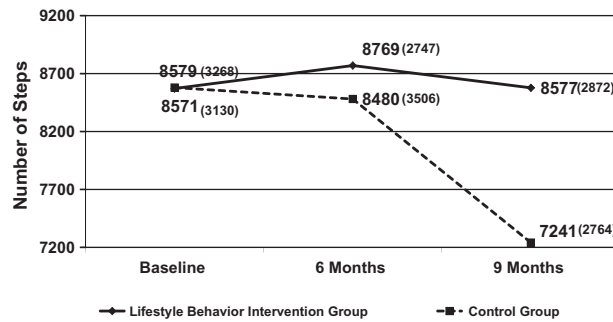


Fig. 2. Accelerometer readings of daily steps, means and standard deviations (SD).

group, approaching a 1000-step decline, whereas intervention participants maintained their activity level. However, results did not show a statistically different pattern between groups for change from baseline to 9 months in average daily minutes in moderate physical activity. Note that women often engaged in short intervals of moderate physical activity rather than long-sustained moderate-to-vigorous activity at baseline (intervention group: mean = 23.44, SD ± 19.16, range 0.75–86.67; control group: mean = 21.83, SD ± 18.69, range 0.17–123.80).

3.4. Cardiometabolic outcomes

Means and SDs for the cardiometabolic variables at baseline, 6 months (post-intervention), and 9 months are presented in Table 2. The main risk factors evident at baseline were obese classification by body mass index,

central adiposity by waist circumference, low HDL-C, and high triglycerides. On average, blood pressures and blood glucose were within normal range at baseline.

Results of the mixed model analyses, controlling for age, were statistically significant for waist circumference ($F[2,213] = 3.26, p = .04$), with the intervention group demonstrating a decrease over the follow-up period; change from baseline was statistically significant at 9 months. Although results of the mixed model analyses for other variables were not statistically significant, the changes for weight and cholesterol for women in the intervention group were in the desired direction.

As described in more detail in the Analysis section, intensity (or “intervention dosage”) was categorized according to class attendance and Teaching and Coaching contacts received. The high intensity subgroup included 51% of the intervention sample; 49% were categorized as

Table 2
Lifestyle and clinical outcome results.

	Lifestyle Behavior Intervention group Mean (SD)			Control group Mean (SD)			Time × group interaction F value
	Pretreatment N = 111	6-Month evaluation N = 98	9-Month evaluation N = 100	Pretreatment N = 112	6-Month evaluation N = 95	9-Month evaluation N = 94	
Behavioral outcomes							
Dietary habits (Lifestyle) ^a	1.80 (.41)	2.23 (.35)	2.26 (.37)	1.77 (.42)	2.03 (.35)	2.08 (.38)	4.87**
Cardiometabolic outcomes							
BMI	32.37 (5.00)	32.04 (5.28)	31.96 (5.30)	32.86 (6.29)	32.44 (6.31)	32.99 (6.48)	1.27
Weight (lbs)	173.65 (29.72)	172.19 (31.63)	171.40 (31.14)	176.45 (35.30)	173.67 (33.95)	176.60 (35.89)	1.25
Waist circumference (cm) ^a	102.31(10.55)	100.78 (11.46)	99.32 (11.37)	100.48 (12.28)	99.75 (12.19)	99.77 (12.66)	3.26*
Blood pressure							
SBP (mm Hg) ^a	111.97 (13.18)	110.20 (13.92)	110.63 (14.29)	116.17 (13.05)	112.77 (12.35)	114.55 (13.01)	.90
DBP (mm Hg) ^a	74.55 (9.14)	73.81 (8.60)	73.13 (9.21)	76.31 (8.78)	76.09 (8.82)	76.18 (9.46)	.78
Cholesterol							
LDL-C (mg/dl) ^a	109.93 (26.67)	108.12 (27.62)	107.85 (26.55)	113.19 (31.62)	115.85 (30.26)	111.83 (29.92)	.21
HDL-C (mg/dl) ^a	42.46 (12.38)	43.31 (18.38)	44.08 (12.71)	46.54 (14.05)	45.97 (17.76)	47.15 (13.69)	.08
Total (mg/dl)	187.26 (31.60)	181.84 (30.90)	185.48 (30.50)	189.61 (36.05)	192.32 (35.69)	189.30 (32.33)	1.69
Triglycerides ^a	172.10 (88.82)	168.08 (115.63)	171.64 (106.53)	157.75 (86.72)	159.87 (104.73)	152.01 (67.19)	.18
Fasting blood							
Glucose (mg/dl)	100.26 (18.56)	101.85 (19.17)	99.31 (17.78)	100.59 (19.08)	100.09 (16.14)	99.44 (17.41)	.30

^a 1–5 cases missing at pretreatment; 1–9 cases missing at 6-month evaluation; & 1–5 cases missing at 9-month evaluation.

* $p < .05$.

** $p < .01$.

Table 3
Intensity analysis: raw means and standard deviations.

	Baseline Mean (SD)	9 months Mean (SD)	p-Value
<i>BMI</i>			.046
High Intensity Group	31.87 (4.65)	31.42 (4.75)	
Low Intensity Group	32.90 (5.34)	32.62 (5.88)	
<i>Weight</i>			.043
High Intensity Group	173.86 (27.71)	171.45 (28.70)	
Low Intensity Group	173.43 (31.95)	171.33 (34.18)	
<i>Waist (cm)</i>			.038
High Intensity Group	102.04 (10.89)	98.38 (11.25)	
Low Intensity Group	102.61 (10.28)	100.46 (11.54)	

low/medium intensity. Results comparing intensity subgroups are displayed in Table 3. Although the differences in means appear relatively small, statistically significant differences by intensity category in improvement from baseline to 9 months were found for body mass index ($t=2.02$, $df=109$, $p=.046$), weight ($t=2.05$, $df=108$, $p=.033$) and waist circumference ($t=2.10$, $df=112$, $p=.038$). The high intensity Lifestyle Behavior Intervention group improved more than the low/medium intensity group for each of these outcomes. There were no significant differences over time by intensity grouping for other outcome measures.

3.5. Cardiovascular disease knowledge

A comparison of pre- and post-test scores on the Heart Knowledge questionnaire for participants in the Lifestyle Behavior Intervention showed a statistically significant change (paired $t=5.69$, $df=89$, $p<.001$), with means of 7.9 ($SD\pm 2.6$) and 9.4 ($SD\pm 1.0$), respectively. This improvement in scores reflects an increase in knowledge from the beginning to end of the group instruction.

4. Discussion

Our Lifestyle Behavior Intervention was planned and implemented with consideration of the specific needs of the immigrant Latinas and the delivery mode and setting most beneficial to them. The nature and design of this study allow a realistic portrayal of what would be expected to occur in a community prevention effort with underserved Latina women. Our findings support the feasibility of implementing the Lifestyle Behavior Intervention. The high retention rates, class attendance, and observations of activities demonstrate that the intervention was acceptable and that the women were comfortable working with promotoras. The Lifestyle Behavior Intervention had a statistically significant and positive effect on dietary habits, patterns of physical activity (daily steps), waist circumference, and knowledge about heart disease (e.g., risk factors, prevention measures). Receiving higher intensity (dosage) of the intervention was modestly beneficial in terms of greater improvement in body mass index, weight, and waist circumference.

Improvement in dietary habits and maintenance of a fairly high level of daily steps may subsequently reduce cardiovascular risk factors such as excessive weight, elevated triglycerides, and low HDL-C levels. Evidence suggests physical activity improves cardiorespiratory fitness and can contribute to reduction in health risk independent of effect on weight (Jakicic and Davis, 2011; Yusuf et al., 2004). The effectiveness of exercise mode, duration, and intensity varies according to risk factor (Vanhees et al., 2012). Although of small magnitude, the decrease in waist circumference observed in the intervention group is notable because of the cardiometabolic risks associated with central fat accumulation (Klein et al., 2007; Yusuf et al., 2004). The mean values for selected clinical variables (i.e., blood pressure, LDL-C, total cholesterol) are in or near goal range at baseline. However, review of our data showed that 23.4% ($n=25$) of the women in the intervention group had baseline LDL-C values at ≥ 130 mg/dL, and the percentage decreased to 16.9% ($n=15$) at the 6-month follow-up. In contrast, the percentage of those in the control group with LDL-C values ≥ 130 mg/dL showed little change over this time period, ranging around 29% ($n=31$). The percent of women with HDL-C values at ≥ 60 mg/dL in the intervention group increased from 6.3% ($n=7$) to 10.3% ($n=10$) over 6 months, while decreasing in the control group. Further increasing HDL-C to desired levels in the relatively short follow-up would be unrealistic given the very low levels at baseline. Our findings support the need for continued efforts to promote therapeutic lifestyle behaviors, as many participants did not engage in 30 min of moderate physical activity, and their lipid profiles could be improved. To achieve target goals for lipids, greater intensity and/or duration of the lifestyle behavior intervention with structured moderate physical activity and healthy dietary habits may be needed. For those women reporting depressive symptoms, increased emotional support also may be required to enhance their ability to make lifestyle changes (Albarrán et al., 2014). Studies show depression is associated with non-adherence to dietary (Aggarwal et al., 2010) and physical activity (Mazzeschi et al., 2012) recommendations.

Our results are consistent with the findings of other community-based studies of promotora-delivered cardiovascular disease risk reduction interventions with Latinos reported by Balcázar et al. (2005, 2010); outcomes included improved dietary habits and greater awareness of cardiovascular disease risk factors. Unlike many studies, we evaluated accelerometer readings rather than self-reported physical activity, because this objective measure is more accurate (Prince et al., 2008; Yokoyama et al., 2001), thereby strengthening the validity of our findings. The average daily step count at baseline reflects a fairly active level of activity that challenges beliefs about the sedentary lifestyle of Latinas and differs from reports on Mexican American women (Office of Minority Health, 2005; Parra-Medina and Hilfinger Messias, 2011; Roger et al., 2012).

The effectiveness of engaging promotoras as facilitators of healthy lifestyle promotion and using a community-based participatory research approach is supported by our findings and past studies (Balcázar et al., 2005; Keller and Cantue, 2008). Viswanathan et al. (2004) found that

community involvement in research improves participation and decreases loss to follow-up. Other researchers have similarly observed that culturally competent community health workers played a key role in minimizing dropout rates, through encouragement and follow-up phone calls (Hayashi et al., 2010). Community-based participatory research trials have very high success rates in recruiting and retaining minority participants and achieving significant intervention effects (De las Nueces et al., 2012).

Through follow-up interviews and focus groups with 18 women in the intervention, we gained enhanced understanding about the important role promotoras fulfilled in the intervention (Albarrán et al., 2014). The women shared how promotoras facilitated behavior change by motivating them through three interconnected elements: tools (e.g., pedometers); knowledge (facts and ideas transmitted within an interactional process); and emotional and social support.

Use of a randomized controlled design in this study strengthens the external validity of our findings by minimizing the potential for selection bias inherent in uncontrolled, nonrandomized studies. Other steps to enhance methodological rigor included calculating sample size to ensure adequate power prior to study implementation, standardizing promotoras' training and activities through protocols and use of curriculum manuals, conducting blinded assessment of outcomes, and adhering to reporting standards (Consolidated Standards of Reporting Trials (CONSORT)) (Moher et al., 2001). The design of this study and clearly defined intervention enhance the utility for replication and inform practical translatability of interventions across settings and populations. Replication studies are needed to evaluate scalability and should include cost-effectiveness analysis (e.g., measures of costs of implementation and costs avoided through prevention). Findings of this type of research will be particularly important in light of proposals related to community health workers. Balcázar et al. (2011) recommend a new paradigm for public health that integrates community health workers into organized community-based prevention efforts. The Institute of Medicine (2002) also has called for greater roles and responsibilities for community health workers in helping to eliminate health inequities among vulnerable populations. Along with interventions aimed at promoting lifestyle behavior changes to prevent diseases, population-based strategies are needed; recommendations of the American Heart Association include modification of the built environment (space created and used by humans for work, living and other activities) to increase physical activity and healthy eating, mass media messages, and public policy to support healthy lifestyles (Pearson et al., 2013). Creating healthy living environments is especially important to immigrant Latinos who often reside in communities with limited resources and environmental risk factors such as inadequate access to affordable fruits and vegetables, lack of walking paths, and safety concerns.

Our study addresses the short-term impact of the Lifestyle Behavior Intervention. Future studies require longer evaluations to determine sustainability of outcomes

and possible delayed effects. The rates of type 2 diabetes and hypertension are based on self-report and our clinical screening evaluations without medical record verifications. For the small number of women being treated with pharmaceutical agents for these conditions, the potential effects of drugs on outcomes could not be evaluated. The multi-component design of this study prevents determination of specific intervention elements (e.g., key messages and activities) that may have significantly influenced participants' behavior and study outcomes. Analysis of exact nutrient intake is not possible with the dietary habits questionnaire that was selected based upon use and acceptability with Latinos. Although several steps were taken to prevent contamination across groups, the possibility of occurrence exists in any community-based intervention. Our findings are not generalizable to the general population or other Latino subgroups but may be applicable to women similar to the study participants. The sample size did not allow detailed examination of differential outcomes for small subgroups of participants with unique combinations of characteristics (e.g., high diastolic blood pressure but normal systolic levels). Findings of this study raise questions for further evaluation that are beyond the scope of this paper, including the temporal sequence of change in lifestyle behaviors and physiologic outcomes; the relationship of outcomes to knowledge development, background characteristics, and participation in the lifestyle behavior intervention; and whether stages of (and intention to) change are influenced by the intervention and act as a mediator on behavioral change. In addition, differential improvement in outcomes should be examined in future analyses, that is, for which subgroups of individuals does the intervention facilitate the greatest amount of improvement?

4.1. Conclusions and recommendations

This clinical trial yields important findings about the positive effects of a community-based intervention on dietary habits, physical activity, and other cardiovascular disease risk factors among immigrant Latinas. Our findings support program facilitation by promotoras and the feasibility of offering lifestyle behavior interventions in community prevention efforts. Culturally tailored interventions to support lifestyle changes and weight loss (Ickes and Sharma, 2012), as well as accessible and affordable health care and linguistically appropriate mass media education are needed to reduce the health risks of these women. We recommend further research to identify methods to intensify group differences found in this study; for example, examining practices of more intense home visitation by promotoras. Strategies for promoting weight loss also should be assessed and the long-term effects evaluated.

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