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Outcomes from a Multiple Risk Factor Diabetes Self-Management Trial for Latinas: ¡Viva Bien!

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Abstract

Background—Culturally appropriate interventions are needed to assist Latinas in making multiple healthful lifestyle changes.

Purpose—The purpose of this study was to test a cultural adaptation of a successful multiple health behavior change program, ¡Viva Bien!

Methods—Random assignment of 280 Latinas with type 2 diabetes to usual care only or to usual care+¡Viva Bien!, which included group meetings for building skills to promote the Mediterranean diet, physical activity, stress management, supportive resources, and smoking cessation.

Results—¡Viva Bien! participants compared to usual care significantly improved psychosocial and behavioral outcomes (fat intake, stress management practice, physical activity, and social–environmental support) at 6 months, and some improvements were maintained at 12 months. Biological improvements included hemoglobin A1c and heart disease risk factors.

Conclusions—The ¡Viva Bien! multiple lifestyle behavior program was effective in improving psychosocial, behavioral, and biological/quality of life outcomes related to heart health for Latinas with type 2 diabetes (ClinicalTrials.gov no: NCT00233259).

Keywords

Latina; Diabetes; Multiple behavior change; Self-management; Randomized controlled trial

Introduction

Diabetes is an independent risk factor for coronary heart disease [1] and appears to be a greater risk factor for US-born Latinas as they have higher mortality from heart disease [2–4]. Relative to non-Hispanic White women and non-Hispanic White and Latino men, Latinas tend to have additional heart disease risk factors, including hypertension, high triglycerides, overweight and obesity, and abdominal body fat [5, 6].

Multiple Risk Factor Interventions

The extent to which individuals consume a healthful diet, maintain a healthful weight, are regularly physically active, avoid smoking, and have access to supportive resources dramatically reduces risk of cardiovascular disease [7–10] and diabetes [11]. These behaviors account for an estimated 50% of premature mortality in the USA [12], yet lifestyle interventions targeting multiple risk factors in addition to diet and physical activity are rare, especially in older women [13], and are almost nonexistent in Latina populations, with a few exceptions [14].

Health Disparities

Disparities in the distribution of health and health care in North America are largely attributable to race/ethnicity and socioeconomic status [15, 16]. With reduced access to quality health care and prevention services, low-income Latinas face a greater risk of diabetes [17]. Latinas represent one of the fastest growing and least affluent ethnic groups in the USA, suggesting that they face poor health outcomes for a variety of chronic diseases [18]. Latinas have higher rates of obesity than non-Hispanic Whites, and Mexican-American adults in particular are twice as likely as non-Hispanic Whites to be diagnosed with diabetes [19]. Studies controlling for socioeconomic status find reduced disparities for some health outcomes, but not for diabetes in Latinas [20, 21]. Thus, traditional socioeconomic status indicators do not explain the health disparities for Latinas in diabetes outcomes. Given the current state of US health care costs and with Latinas expected to constitute 30% of the US population by 2050 [22], there is a critical need for effective interventions, especially in high-risk groups such as Latinas having diabetes, that address lifestyle and prevention of diabetes complications such as coronary heart disease.

Emerging public health models advocate an appropriate response to diabetes disparities in minority health care, such as delivering culturally sensitive diabetes interventions [23]. The goal of the ¡Viva Bien! study was to adapt and evaluate an established, evidence-based lifestyle change program for an underserved population at high risk for coronary heart disease: Latinas with type 2 diabetes.

The purpose of this paper was to document the extent to which the ¡Viva Bien! intervention helped Latinas with type 2 diabetes make simultaneous changes in psychosocial factors and multiple lifestyle behaviors that were hypothesized to result in improved biologic and quality of life outcomes at 6 and 12 months.

Methods

Study Design

The ¡Viva Bien! program was an adaptation and evaluation of an established evidence-based lifestyle change program for an underserved population at high risk for heart disease: Latinas with type 2 diabetes [24]. The research team demonstrated the prior effectiveness of this program in mostly non-Hispanic White women in Oregon [25, 26]. In the cultural

adaptation of ¡Viva Bien!, we addressed sociocultural, economic, and environmental contexts important for Latinas [27].

The ¡Viva Bien! intervention was designed from an implicit logic model in which intervention activities were hypothesized to improve the psychosocial variables of problem solving, social support, and self-efficacy. Those psychosocial variables, in turn, were hypothesized to lead to improvements in lifestyle behaviors such as physical activity, reduced fat consumption, and utilization of resources that support the self-management of chronic illness [28–30]. Finally, improvements in lifestyle behaviors were hypothesized as mechanisms for changing hemoglobin A1c, heart disease risk, and health-related quality of life [31–34].

We recruited patients from nine Kaiser Permanente clinics in the Denver, CO, metropolitan area, and one large community health center, the Salud Family Health Center, located in Commerce City near Denver. Kaiser Permanente Colorado is a managed care organization that services approximately 450,000 patients in the Denver metropolitan area, about 17% of whom are Latinos. Salud is a community health center that provides comprehensive primary health services to low-income patients who may lack private insurance and have little or no access to other health care providers. About 65% of Salud's patients are Latinos whose primary language is Spanish.

Inclusion criteria were self-identified Latina ethnicity, 30–75 years of age, diagnosis of type 2 diabetes for at least 6 months identified by electronic medical record codes and using the Welborn criteria [35], living independently, having a telephone, ability to read in either English or Spanish, not developmentally disabled, and living close enough to the intervention site to attend weekly meetings. Exclusion criteria included being on an insulin pump or having end-stage renal disease. Participants were recruited [27] (Fig. 1) in four waves, with roughly one fourth of the sample participating in each wave. In order to sample from different socioeconomic levels, each of the four waves was recruited from a different geographic area.

Letters in English and Spanish, signed by the project's Latino physician, were mailed to potential participants, along with self-addressed stamped postcards that could be returned to decline further contact or request more study information. Women who did not return postcards or requested further information were telephoned by bilingual project recruiters who described the program, confirmed eligibility and Latina identity, and invited qualified candidates to participate. Those who agreed were scheduled to visit either a Kaiser Permanente Colorado or Salud location where they completed formal consent procedures and baseline assessments. To reduce participation barriers, the project offered flexible assessment times, bilingual staff and materials, and free transportation.

Assessors were blinded to the treatment assignment of each participant at the baseline assessment only, prior to randomization. After that, assessors were aware of treatment assignments. To limit the potential of biasing results, we created a detailed assessment protocol and closely supervised assessors to ensure that the protocol was followed. Much of the assessment did not involve assessors and therefore could not be biased by their knowledge of treatment assignment. Participants filled out surveys in private without direct supervision of the assessors. Blood tests were conducted by phlebotomists and laboratories outside of the study staff. For the few measurements that assessors made of the participants (height, weight, blood pressure), calibrated tools were used (e.g., scales) to ensure accuracy and limit bias.

The research protocol was approved by the Kaiser Permanente Colorado and Oregon Research Institute institutional review boards, and all participants gave written informed consent. Data were collected from 2006 to 2010.

Treatment Protocol

Participants who completed baseline assessments ($N=280$) were randomized to receive usual care only or to receive usual care plus the intervention based on a computerized random number generator. Random assignments were made by assessors after each participant's first (baseline) assessment. Separate lists were used for smokers and nonsmokers to stratify by the smoking variable to ensure equal representation of smokers in the two conditions. Randomization procedures resulted in a final sample consisting of approximately equal numbers of participants in each condition.

The ¡Viva Bien! program included a 2.5-day retreat followed by weekly meetings and encouraged participants to (a) follow the Mediterranean diet adapted for Latin American subcultures, (b) practice stress management techniques daily, (c) engage in 30 min of daily physical activity, (d) stop smoking, and (e) take part in problem solving-based support groups. The purpose of the retreat was to introduce each of the major components of the program and provide time for participants to practice new skills. After the retreat, the intervention continued with 4-h facilitator-led meetings, providing 1 h each of instruction and practice of diet, stress management, physical activity, and support groups (1 h for each component=4 h). Meetings were held weekly for 6 months, then faded to twice monthly for 6 months.

Cultural adaptation of the program has been detailed in two papers [24, 36]. The adaptation was conducted with a participant-focused iterative process, which included: (a) information gathering from literature review and focus groups, (b) preliminary adaptation design in which the intervention was modified based on findings from the previous step, and (c) a preliminary adaptation test, a pilot study that found participants were highly satisfied with the intervention and showed improvement across diverse outcomes [24, 36]. Much like other cultural adaptations of nutrition and exercise interventions for Latinos [37], the ¡Viva Bien! adaptation included greater family involvement, foods common in Latin American countries that could be used in modified Mediterranean diet recipes, and incorporation of Latin music, language, and symbols in meetings and materials. Adaptations are summarized in the Appendix.

Measures

Baseline assessments were conducted in two, one-on-one sessions, with follow-up assessments at 6 and 12 months for all participants. Those in the usual care-only condition received \$25 gift cards for assessment completion.

Problem-solving ability was assessed using the Diabetes Problem-Solving Interview [38] and coded by interviewers blind to condition. Self-efficacy was assessed using the Confidence in Overcoming Challenges to Self-Care instrument [39]. Social support was assessed using the UCLA Social Support Inventory [40], which measures several types, sources, and dimensions of supportive resources as well as satisfaction with these resources. The semiquantitative food frequency questionnaire developed at the Fred Hutchinson Cancer Research Center [41] was used to document percent of calories from saturated fat. Stress management practice was assessed using a self-monitoring log which tracked daily minutes of yoga stretches, breathing exercises, progressive relaxation, and meditation and visualization. The stress management practice score was calculated as the number of self-monitored minutes of these activities averaged across 7 days [25]. The Modified

International Physical Activity Questionnaire was used to calculate the number of days per week participants engaged in physical activity [42], rather than other variables that may be derived from the physical activity inventory, because days/week was specifically targeted by the ¡Viva Bien! intervention. The Brief Chronic Illness Resources Survey [43] provided a profile of an individual's support for behavior-specific disease management ranging from more proximal support (e.g., family and friends) to more distal factors (e.g., neighborhood or community). For the present analyses, the total Chronic Illness Resources Survey score was used to represent engagement in social–environmental support activities. The Chronic Illness Resources Survey [44], physical activity inventory [45], food frequency questionnaire [46], and diabetes problem-solving measure [28] had established psychometric properties with Latinas prior to the start of the present research. The barriers questionnaire was tested for the first time with Latinas, in the pilot study ($n=12$) prior to the beginning of the ¡Viva Bien! trial, and was shown to be sensitive to change. Dunkel-Schetter and colleagues used portions of the UCLA Social Support Inventory in research on Latinas' pregnancy and birth outcomes (e.g., [47, 48]), but not the entire scale. Concurrent validity was indicated in the present study with a correlation of 0.36 between the UCLA Social Support Inventory and Brief Chronic Illness Resources Survey.

Measures of height and weight were taken, if possible, in the morning in the fasting state and in stocking feet on a sensitive digital scale (Detecto Electronics). Hemoglobin A1c assays were performed at the Kaiser Permanente Colorado Regional Reference Laboratory in Aurora, CO, and measured on a Bio-Rad Variant II Turbo liquid by high-pressure liquid chromatography. Health-related quality of life was assessed using the core Centers for Disease Control and Prevention (CDC) Healthy Days measure. From this instrument, the present study employed two measures: (a) the number of recent days when physical health was not good and (b) the number of recent days when mental health was not good [49]. Ten-year heart disease risk was assessed using the United Kingdom Prospective Diabetes Study logistic equation [50]. This model is diabetes-specific, has been demonstrated to strongly predict occurrence of coronary heart disease among diabetes patients, and incorporates hemoglobin A1c, systolic blood pressure, and ratio of total cholesterol to high-density lipoprotein as risk factors in addition to age, sex, ethnic group, smoking status, and time since diabetes diagnosis. At each assessment, participants also were asked whether they had smoked a cigarette in the past 7 days and listed their current diabetes-related medications (oral hypoglycemic, insulin, antihypertensive, cholesterol, depression, glucocorticoid, aspirin, and others).

Statistical Analysis

All data were entered and verified, and scores were calculated for multiple-item instruments. Repeated measures multivariate analyses of covariance (MANCOVA) were used to test for hypothesized treatment effects on psychosocial, behavioral, and biological/quality of life outcome measures from baseline to 6 and 12 months. The baseline value of the dependent variable was covaried in all analyses. Age also was covaried as it was found in univariate correlational analyses to be significantly associated with most outcomes at baseline. Though length of diagnosis of diabetes also was significantly correlated with outcomes at baseline, it was not included in MANCOVAs to avoid multicollinearity since it was also significantly correlated with age. BMI was covaried in analyses of Chronic Illness Resources Survey-measured use of supportive resources, saturated fat intake, and hemoglobin A1c as BMI was significantly related to these variables at baseline. In order to assist readers in directly comparing results across different measures and different units, effect sizes (Cohen's d , defined as mean/SD) were calculated on difference scores from baseline. We followed Cohen in interpreting effect sizes as 0.2=small, 0.5=medium, and 0.8=large. Actual values for all measures in original units are provided in the tables, for both intent-to-treat and

imputed analyses, to help interpret the clinical significance of the findings. Statistical analyses were conducted using SPSS 12.0 (SPSS Inc., Chicago).

All repeated measures analyses were performed two ways. First, intention-to-treat analyses were conducted after missing data were imputed using multiple imputation procedures via the expectation–maximization algorithm with NORM software. Second, a complete-case approach was used in which participants with missing follow-up data on the outcome variable of interest were excluded. Both complete-case and intention-to-treat results are presented in the tables for comparison; intention-to-treat analyses were used as the primary outcome results.

Partial correlations (partialling out age and change in BMI) were computed to examine the relations between change in psychosocial, behavioral, and biological/quality of life variables at both 6-month and 12-month follow-up.

The study was powered (85%, two-tailed alpha of 0.05) to detect an effect size of 0.40 averaged across psychosocial, behavioral, biological, and quality of life outcomes with $N=220$ participants at 6- and 12-month follow-up, assuming 20% attrition from baseline.

Results

Participants

Participation results have been reported previously [27] and are summarized in Table 1. The study was successful in recruiting a diverse, relatively high-risk sample of Latina women. Eighty-three percent of female patients with type 2 diabetes who were initially contacted by letter were ineligible because they were not Latina. A total of 280 women participated, 61% of those confirmed eligible. On average, participants were between 55 and 60 years of age, (mean=57.11; SD=10.09), had been diagnosed with diabetes for almost 10 years, were obese (mean BMI=34.3 kg/ m²), and had a baseline hemoglobin A1c level >8. Approximately two thirds reported an annual family income of less than \$50,000, and more than half had a high school education or less. The recruited sample was fairly well acculturated, with 40.8% mostly Anglo-oriented, 24.3% somewhat Anglo-oriented, 17.6% mixed Latino- and Anglo-oriented, 4.8% somewhat Latino-oriented, and 12.5% mostly Latino-oriented [24]. Sixteen percent preferred Spanish to English, and health literacy scores were considerably lower than we have found in prior diabetes projects.

Despite randomization, there were three (of 17 tested) significant baseline differences between conditions on participant characteristics: age, BMI, and years diagnosed with diabetes. Usual care participants were older, had diabetes longer, and had lower BMI than ¡Viva Bien! participants.

Approximately 22% of participants did not complete the 6-month assessment, with no significant differences between conditions in attrition (21.7% attrition for usual care vs. 23.2% for ¡Viva Bien!).

Psychosocial Outcomes

There were large and consistent differences between conditions on change in the psychosocial variables hypothesized to be influenced by the intervention (Table 2). The ¡Viva Bien! condition improved considerably more than the usual care condition by the 6-month follow-up on measures of problem solving, self-efficacy, and perceived support in both intention-to-treat and complete-case analyses. Effect sizes for these differences ranged from 0.32 to 0.89. Differences were essentially maintained at the 12-month follow-up.

Behavior Change

Between-condition effects were found on four targeted behavioral outcomes (Table 3), but not on smoking prevalence (there were 17 smokers in the usual care condition and 13 smokers in the ¡Viva Bien! condition). The ¡Viva Bien! intervention produced significant improvements relative to the usual care condition by the 6-month follow-up on percent of calories from fat, practice of stress management, days per week exercised, and engagement in social–environmental support activities. Across the behavioral outcomes, effect sizes at 6 months ranged from 0.20 to 1.00, with the magnitude of the impact on the dietary outcomes especially large. Treatment effects generally were not maintained at the 12-month assessment as the usual care condition had improved on some of the behavioral outcomes.

Biological and Quality of Life Outcomes

Biological and quality of life outcomes revealed an encouraging albeit not totally consistent pattern of results (Table 4). The ¡Viva Bien! condition improved significantly more than the usual care condition on hemoglobin A1c and 10-year heart disease risk. However, physical and mental health were not significantly improved. The magnitude of effect at 6 months was moderate, with effect sizes of 0.23 and 0.48 for heart disease risk and hemoglobin A1c, respectively. At the 12-month follow-up, intervention effects generally decreased, with the exception of an increased effect on the physical health scale of the CDC Healthy Days measure.

Relations Among Outcomes

A number of partial correlations between outcomes were significant, especially those relating change in psychosocial with behavioral variables and those relating change in behavioral with physiologic variables.

Psychosocial with Behavioral Outcomes—From baseline to 6 months, change in problem solving, self-efficacy, and UCLA-measured social support significantly correlated with change in saturated fat intake and the use of chronic illness resources. There were additional significant relations for self-efficacy and UCLA-measured social support change in stress management practice and physical activity from baseline to 6 months. Some of these relations remained significant at 12 months.

Behavioral with Physiological Outcomes—From baseline to 6 months, change in saturated fat intake and in use of chronic illness resources significantly correlated with change in hemoglobin A1c. Also, change in the use of chronic illness resources correlated with change in physical health. These relations were nonsignificant at 12 months. However, baseline to 12-month change in stress management practice was related to change in hemoglobin A1c over the same time period.

Psychosocial with Physiological Outcomes—Few relations were significant between change in psychosocial variables and change in biological/quality of life variables from baseline to either 6 or 12 months. Change in the UCLA-measured social support was significantly related to change in hemoglobin A1c at both 6 and 12 months, and change in self-efficacy significantly correlated with change in physical health at 12 months (Table 5).

Attendance

Attendance at ¡Viva Bien! sessions was variable. Weekly meeting attendance during the first 6 months averaged 58% and declined to 48% for meetings between 6 and 12 months. Of those giving a reason for non-attendance, the most frequent was illness (9.9%), followed by work-related conflicts (4.5%), being on vacation (4.2%), or having a social conflict (3.7%).

Partial correlational analyses (partialling out the effects of baseline values on 6-month outcomes) indicated that percent of meetings attended was significantly associated at 6 months with self-efficacy (partial $r=0.25$, $p=0.012$), social support (partial $r=0.21$, $p=0.031$), stress management practice (partial $r=0.27$, $p=0.009$), exercise (partial $r=0.29$, $p=0.003$), use of supportive resources (partial $r=0.20$, $p=0.040$), hemoglobin A1c (partial $r=-0.28$, $p=0.004$), and 10-year heart disease risk (partial $r=0.51$, $p<0.001$), but not with problem solving, saturated fat intake, or healthy days.

Medications

MANCOVAs investigating self-reported changes in the taking of diabetes-related medications (oral hypoglycemic, insulin, antihypertensive, cholesterol, depression, glucocorticoid, aspirin, and others) were nonsignificant ($p>0.05$), indicating that medication taken in the usual care and ¡Viva Bien! conditions did not differ significantly and would not explain changes in outcomes.

Discussion

The substantive findings presented in this manuscript make several unique and important contributions to existing multiple behavior change intervention research. This randomized clinical trial addresses obesity and diabetes and links multiple behavioral lifestyle change to positive behavioral, psychosocial, and biological outcomes in Latina patients with type 2 diabetes. This is an underserved, understudied, and growing population in the USA that is at especially high risk of coronary heart disease and that carries an especially high medical burden. The study replicates a previously successful evidence-based multiple risk factor intervention with a different setting, population, geographic location, and set of interventionists [25].

Over the 12-month lifestyle change intervention, Latinas with type 2 diabetes reduced their risk for adverse diabetes outcomes by lowering hemoglobin A1c, a key biologic outcome. While the reductions in A1c may seem modest, the ¡Viva Bien! treatment condition reduced A1c by 0.8% from baseline to 6 months in complete-case analysis ($8.5\% - 7.7\% = 0.8\%$) and significantly more than the control condition. This reduction is comparable to the improvements in A1c demonstrated by some diabetes medications and can be expected in addition to pharmacologic interventions. Epidemiological analysis of the United Kingdom Prospective Diabetes Study data [51] showed that for every percentage point decrease in A1c, there was a 35% reduction in risk of complications. In our study, this would translate to a 28% reduction in risk of diabetes complications and could translate over longer periods of time to improved outcomes related to heart attack and cardiac death. While the United Kingdom Prospective Diabetes Study risk assessment was not specifically validated to measure change, there is precedent in the literature for calculating 10-year cardiovascular disease risk reductions using risk equations [52], and the variables from which the United Kingdom Prospective Diabetes Study measure is derived are appropriate for measuring change (that is, patients are considered to be making clinical progress when they modify their smoking status, systolic blood pressure, hemoglobin A1c, and cholesterol level).

The ¡Viva Bien! program was successful in promoting short-term biological improvements. The fading of effect at 12 months is instructive. This may be a direct result of the fading of the intervention. Maintenance of behavior change is an important and neglected area of health behavior research, and more research is needed to find ways to sustain health behaviors over the life course in the same way that pharmacologic therapy may be prescribed to maintain health over the long term.

Participants improved on four targeted behavioral outcomes, but not smoking prevalence. They decreased saturated fat consumption, increased physical activity and stress management practices, and increased their use of social–environmental supportive resources. Women who participated in ¡Viva Bien! improved psychosocial variables such as social support, problem solving, and self-efficacy, which have been linked to health behavior change. The improvements attributable to the ¡Viva Bien! intervention were impressive in their magnitude and diversity of outcomes. Six-month effect sizes across 12 outcomes averaged 0.48 in complete-case analyses and 0.37 in intention-to treat analyses.

The pattern of correlational findings among psychosocial, behavioral, and physiological outcomes provided evidence that the intervention operated as theorized; that is, the treatment prompted changes in psychosocial variables which were related to changes in behavioral variables, which themselves were related to changes in physiologic variables—but there were few significant relations between psychosocial variables and physiological variables directly.

¡Viva Bien! yielded effect sizes similar to those obtained in the evidence-based Mediterranean Lifestyle Program from which it was adapted. Respectively for ¡Viva Bien! and the Mediterranean Lifestyle Program, effect sizes at 6 months were 0.48 vs. 0.27 for problem solving, 0.59 vs. 0.35 for self-efficacy, 0.89 vs. 0.67 for social support, 1.00 vs. 0.67 for saturated fat intake, 0.35 vs. 0.50 for stress management practice, and 0.36 vs. 0.67 for physical activity.

Health care reform discussions increasingly recognize the need to address lifestyle changes to prevent type 2 diabetes or, for those who have diabetes, its complications, emphasizing wellness, prevention, and personal behaviors [53, 54]. This need may be more pronounced in populations experiencing health and health care disparities, such as Latinas. One way to reduce disparities in diabetes outcomes for Latinas is to develop and test culturally appropriate, efficacious lifestyle interventions that reach and engage them, goals that were largely achieved in this study [24]. Just as research with men cannot necessarily be generalized to women, research with non-Hispanic Whites (with whom most studies of heart disease have been conducted) cannot be assumed to generalize to other ethnicities. The extant literature provides little guidance about whether conventional strategies (e.g., weight loss, increased physical activity, quitting smoking, culturally adapted Mediterranean diets, supportive resources) are useful for reducing heart disease risk in Latinas with type 2 diabetes. Our cultural adaptation for Latinas of the previously established Mediterranean Lifestyle Program was successful in prompting Latinas to modify heart disease risk behaviors despite their generally poor baseline dietary and physical activity habits. The ultimate goal is to demonstrate that beneficial lifestyle practices and health improvements can be maintained over time and that such programs are cost-effective.

Limitations of this study include investigation within a single managed care setting and community clinic, as well as use of several self-report measures. Our purpose in recruiting patients from two different populations (Kaiser Permanente Colorado and a community health center) rather than one was to increase the generalizability of results. Most of the self-report measures have been validated against more objective standards, but it is not known whether possible inaccuracies of self-reporting in this study influenced the observed results. Another possible limitation is that despite randomization, statistically significant baseline differences were found between the usual care and ¡Viva Bien! conditions on 3 of 17 participant characteristics tested. This sometimes occurs in randomized samples, and in the present study, the few differences in participant characteristics were accounted for in subsequent analyses. Overall, a range of older and younger, lighter and heavier participants were randomized into each group. Cost of the intervention presents a potential limitation.

The cost of ¡Viva Bien!, though greater than typical diabetes education interventions, is relatively low when compared to other medical treatment options for the prevention and treatment of heart disease, such as angioplasties and stents in stable individuals [54, 55]. Another limitation was the use of the International Physical Activity Questionnaire (a) to calculate days/week of exercise rather than other variables using the standard scoring and (b) to measure physical activity in 16% of the study sample aged 70 years or older since the International Physical Activity Questionnaire has been validated for those aged 15–69 years. Our results regarding physical activity should therefore be read cautiously.

Attendance at ¡Viva Bien! weekly meetings declined from 58% during the first 6 months to 48% for meetings between 6 and 12 months, in part because the study sampled a broad population consisting of a number of individuals who may have found it challenging to integrate the ¡Viva Bien! principles into their daily lives. Reasons for missing meetings were systematically collected and coded, and the most frequently stated reasons for missing meetings included illnesses, work-related conflicts, vacations, and social conflicts. Qualitative data suggested, counterintuitively, that habitual attendance of a biweekly meeting was more challenging than weekly meetings. Bonding occurred between staff and participants, and participants with each other, and participants stated that they believed someone was there for them. When the meeting schedule decreased, there was a feeling of abandonment more directed to staff than other participants. Also, the perceived consequences of missing the biweekly meeting may have been greater with regard to sustained engagement and commitment to the program. Once a participant missed a session, it seemed that missing future meetings became more frequent. However, only one woman specifically offered this as a reason for missing a meeting.

We anticipated wide variations in adherence to the intervention, ranging from participants who would do nothing to participants who would fully embrace all program components. Within this context, the mean attendance rate of 58% at 6 months is reasonable. Attendance may have been higher if we had recruited a convenience sample, such as is obtained in studies relying on advertisements or individuals who proactively contact a project office, or if we had screened out all except the most highly motivated women with few real life problems or competing family demands. In a practical or clinical program, which would not involve a control group and for which participants would self-enroll, motivation and adherence would likely be greater. Those with better attendance generally had better outcomes, as found in other studies with interventions of similar intensity [56, 57].

Despite the fact that some participants attended more often than others, the intervention produced impressive and consistent changes in behavioral, psychosocial, and biologic outcomes overall, which adds weight to the findings. This is a complex community-based practical research trial that must be evaluated against standards and methodological criteria appropriate for non-pharmacologic effectiveness trials.

Strengths of the study include a reasonably large, high-risk, and underserved sample; cultural adaptation of an evidence-based program; focus on and improvement of multiple lifestyle behaviors known to reduce heart disease risk; inclusion of a number of psychosocial, behavioral, biological, and quality of life outcome measures; the randomized design; and the inclusion of both complete-case and intention-to-treat analyses.

Overall, results of this study move behavior change theory forward by demonstrating that a health intervention promoting multiple, rather than single, behavioral change is feasible and effective. Health behaviors are neither isolated nor sequential. Especially for people with chronic illnesses, such as diabetes, multiple behaviors work together to influence well-being, and behavior changes must be addressed simultaneously. The ¡Viva Bien! program

succeeded in helping participants develop new skills to change multiple diabetes-related behaviors. Although not all participants engaged in all behaviors equally well, they improved their outcome expectations and their self-efficacy related to performing behaviors and managing their diabetes. These results suggest that clinicians and researchers should pursue health interventions focusing on multiple behavior, rather than single behavior, change.

Future research recommendations include examination of intervention maintenance effects beyond 12 months, identification of mediators and moderators of outcomes, and cost effectiveness analyses to determine the readiness of ¡Viva Bien! for translation into practice.

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Appendix

Table 6

¡Viva Bien! intervention components and cultural adaptation

Intervention	Cultural adaptation
Initial 2.5-day retreat	
The retreat kicked off the program and encouraged bonding between participants and with staff. The retreat featured explanations and practice of all ¡Viva Bien! program components: Mediterranean diet meals (catered) Physical activity (aerobic and strength) Stress management Social support groups Smoking cessation	The retreat was conducted by bilingual staff, who gave presentations in English and Spanish. English and Spanish PowerPoint slide shows and handouts were provided, illustrated with photographs of Latina women. Adaptations to specific program components are provided below.
Meetings	
Four-hour meetings were weekly for the first 6 months, and bimonthly for months 7–12. They consisted of 1 h each of: Mediterranean diet (potluck) Physical activity Stress management Social support groups	Family nights were added at the end of 6 months to inform family members of participants' intervention activities and to celebrate their achievements. Family nights were vehicles for increasing the families' support for participants' intervention engagement. Presentations and question-answer sessions with project's Latino physician also were added at the suggestion of participants who wanted the opportunity to ask questions they were unable to ask their personal health care providers.
Program components	
1. Mediterranean diet	
Participants were instructed to follow tenets of the Mediterranean diet emphasizing vegetables, fruits, legumes, nuts, cereals, olive oil, limited animal fat, and portion control.	The Latina project dietitian altered Latin American recipes to conform to the ¡Viva Bien! diet by lowering the fat and calories while maintaining flavor with traditional ingredients and spices. Because Latinas represent a diverse group, there is no typical "Latino diet." Thus, recipes from specific Latin American countries were modified, using common staples. The challenge was to cover the wide range of ethnic Latin American foods. Potluck dinners were a central part of the diet component. Cooking demonstrations by the Latina dietitian showed new methods for preparing typical foods. Participants were encouraged to modify their favorite recipes by incorporating the principles of the Mediterranean diet into their usual foods. Attention was paid to acceptance and support from family members who might also benefit from these dietary changes. Colorful pamphlets were created to help participants follow the diet. The pamphlets were available in English and Spanish, and included photographs of common Latino foods as well as Latina women.
2. Physical activity	
Participants were asked to engage in moderate aerobic activity 30 min most days per week, and 10 strength training exercises performed two times per week.	During the physical activity sessions at the retreat and meetings, participants were given the choice of walking outside or following a trained instructor in an aerobics class led in both English and Spanish, with Latin (e.g., salsa) style steps and music. By giving participants choices, women could determine for themselves which physical activities were culturally appropriate. Colorful pamphlets were created to support participants' physical activity. The pamphlets were available in English and Spanish, and

Intervention	Cultural adaptation
3. Stress management	included photographs of Latina women. Also created for the program were take-home exercise CDs available in English and Spanish.
Participants were asked to practice stress management techniques for at least 1 h per day, including 20 min of yoga stretches, 15 min of progressive deep relaxation, 15 min of meditation, and 5 min of directed or receptive imagery.	Created for the program were take-home stress management CDs available in English and Spanish. The research team considered making adaptations to the stress management component, believing that yoga and meditation practices may be perceived as religious activities incongruent with Latina participants' cultural experiences. But focus group participants did not raise any concerns, and the yoga and meditation components were retained.
4. Social support	
Regular meetings included 1 h of group support. Support group sessions included structured mini-units (e.g., problem solving, social support, pleasant activities, negative thoughts, goal setting) and unstructured "check-in" sessions when participants discussed successes and barriers to lifestyle change.	To accommodate language preferences, participants were offered groups conducted primarily in English or Spanish. The flexible nature of the support-group structure allowed participants to choose topics for discussion that were personally relevant and culturally appropriate. Handout materials created for mini-units were available in English or Spanish.
5. Smoking cessation	
Participants who smoked were encouraged to set a quit date and stop.	Colorful pamphlets were created for the program to help participants stop smoking. The pamphlets were available in English and Spanish. Smoking cessation sessions were led by a bilingual facilitator.

Fig. 1.
CONSORT diagram of ¡Viva Bien! study participation

Table 1

Baseline characteristics of participants by treatment condition

Characteristic	<i>M</i> (SD) or %		Group differences (<i>p</i> value)
	Usual care (<i>n</i> =138)	¡Viva Bien! (<i>n</i> =142)	
Age	58.7 (10.3)	55.6 (9.7)	0.009
Body mass index (kg/m ²)	33.2 (6.7)	35.3 (7.0)	0.010
Years diagnosed with diabetes	10.4 (9.8)	8.4 (6.5)	0.049
Current smoker (% Yes)	12.6	9.2	0.368
Income			0.133
\$0 to \$29,999 (%)	50.0	36.8	
\$30,000 to \$49,999 (%)	21.7	27.1	
\$50,000 to \$69,999 (%)	13.3	16.5	
\$70,000 to \$89,999 (%)	10.0	8.3	
\$90,000 or more (%)	5.0	11.3	
Type of glucose-lowering medication			0.181
None or oral only (%)	67.8	70.9	
Insulin only (%)	13.1	5.7	
Insulin + oral medication (%)	19.0	23.4	
Level of education			0.450
0 to 11th grade (%)	27.1	20.0	
High school graduate (%)	27.8	32.1	
Some college (%)	30.1	28.6	
College/university graduate (%)	15.0	19.2	
Prefer Spanish (%)	14.7	17.0	0.633
Health literacy	4.2	4.3	0.460
Numeracy total	3.5 (1.2)	3.7 (1.1)	0.258
Numeracy preference	3.5 (1.2)	3.7 (1.1)	0.235
Numeracy ability	3.4 (1.6)	3.6 (1.5)	0.310

Based on chi-square and *t* tests, as appropriate

Table 2

Psychosocial outcomes at 6 and 12 months

Baseline <i>M</i> (SD)						6 months <i>M</i> (SD)	12 months <i>M</i> (SD)	Condition <i>F</i> value	Condition by time <i>F</i> value
Quality of problem-solving strategies									
Intention-to-treat (<i>n</i> =270)									
Usual care	4.3 (0.4)	4.2 (0.5)	4.2 (0.4)	19.49**	0.15				
¡Viva Bien!	4.3 (0.5)	4.4 (0.4)	4.4 (0.4)						
Effect size		0.32	0.38						
Complete cases (<i>n</i> =169)									
Usual care	4.2 (0.4)	4.2 (0.5)	4.1 (0.4)	32.31***	1.62				
¡Viva Bien!	4.3 (0.5)	4.4 (0.4)	4.5 (0.3)						
Effect size		0.48	0.45						
Self-efficacy									
Intention to treat (<i>n</i> =277)									
Usual care	3.2 (0.7)	3.3 (0.8)	3.3 (0.8)	9.08**	1.82				
¡Viva Bien!	3.1 (0.7)	3.5 (0.7)	3.4 (0.7)						
Effect size		0.40	0.25						
Complete cases (<i>n</i> =174)									
Usual care	3.3 (0.7)	3.2 (0.7)	3.2 (0.8)	24.56***	1.51				
¡Viva Bien!	3.1 (0.8)	3.6 (0.7)	3.5 (0.7)						
Effect size		0.59	0.40						
UCLA positive summary score									
Intention to treat (<i>n</i> =277)									
Usual care	2.4 (0.7)	2.6 (0.7)	2.6 (0.7)	71.20***	0.13				
¡Viva Bien!	2.5 (0.7)	3.2 (0.8)	3.1 (0.7)						
Effect size		0.75	0.57						
Complete cases (<i>n</i> =174)									
Usual care	2.4 (0.7)	2.6 (0.7)	2.5 (0.7)	64.73***	1.61				
¡Viva Bien!	2.5 (0.7)	3.3 (0.7)	3.2 (0.7)						
Effect size		0.89	0.66						

Based on repeated measures MANCOVAs with age and the baseline value of the dependent variable covaried. Unadjusted means are presented in the table. Multivariate F statistics (the ratio of the model mean square to the error mean square) and significance values derived from MANCOVAs are provided for the treatment effect (condition F value; degree of freedom=1) and for the treatment effect over time (condition by time F value; degree of freedom=1). The larger and more significant the F statistic, the more likely the intervention produced effects across time

* $p < 0.05$;

** $p < 0.01$;

*** $p < 0.001$

Table 3

Behavioral outcomes at 6 and 12 months

	Baseline <i>M</i> (SD)	6 months <i>M</i> (SD)	12 months <i>M</i> (SD)	Condition <i>F</i> value	Condition by time <i>F</i> value
% Calories saturated fat					
Intention to treat (<i>n</i> =266)				9.33***	11.25**
Usual care	0.11 (0.03)	0.10 (0.03)	0.10 (0.03)		
¡ Viva Bien!	0.12 (0.03)	0.09 (0.03)	0.10 (0.03)		
Effect size		0.67	0.00		
Complete cases (<i>n</i> =152)				17.42***	13.05***
Usual care	0.11 (0.03)	0.11 (0.02)	0.11 (0.03)		
¡ Viva Bien!	0.11 (0.03)	0.09 (0.02)	0.09 (0.02)		
Effect size		1.00	0.33		
Stress management daily practice (min)					
Intention to treat (<i>n</i> =270)				19.49***	0.15
Usual care	4.3 (0.4)	4.2 (0.5)	4.2 (0.4)		
¡ Viva Bien!	4.3 (0.4)	4.4 (0.4)	4.4 (0.4)		
Effect size		0.32	0.38		
Complete cases (<i>n</i> =155)				8.92**	1.33
Usual care	4.8 (7.0)	3.3 (4.0)	4.2 (4.6)		
¡ Viva Bien!	4.3 (7.1)	5.1 (5.3)	5.1 (5.6)		
Effect size		0.35	0.21		
Smoking prevalence (%)					
Intention to treat (<i>n</i> =271)				3.00	0.11
Usual care	12.6 (33.0)	10.8 (31.1)	11.5 (32.1)		
¡ Viva Bien!	9.2 (29.0)	9.2 (29.0)	10.6 (30.9)		
Effect size		0.08	0.20		
Complete cases (<i>n</i> =172)				2.63	1.02
Usual care	10.2 (30.5)	9.1 (28.9)	9.1 (28.9)		
¡ Viva Bien!	6.0 (23.8)	4.8 (21.4)	7.1 (25.9)		
Effect size		0.14	0.23		
Physical activity days/week (IPAQ)					

	Baseline <i>M</i> (SD)	6 months <i>M</i> (SD)	12 months <i>M</i> (SD)	Condition <i>F</i> value	Condition by time <i>F</i> value
Intention to treat (<i>n</i> =277)				2.94	0.16
Usual care	4.1 (2.8)	5.1 (2.4)	6.4 (4.3)		
¡Viva Bien!	4.2 (2.7)	5.8 (2.2)	6.9 (4.4)		
Effect size		0.20	0.09		
Complete cases (<i>n</i> =179)				5.58*	0.00
Usual care	4.5 (2.7)	5.1 (2.4)	6.3 (4.4)		
¡Viva Bien!	3.8 (2.8)	5.9 (2.1)	7.1 (4.3)		
Effect size		0.36	0.26		
Chronic illness resources survey total score					
Intention to treat (<i>n</i> =277)				22.31***	2.05
Usual care	2.1 (0.6)	2.1 (0.6)	2.2 (0.6)		
¡Viva Bien!	2.1 (0.7)	2.4 (0.7)	2.3 (0.7)		
Effect size		0.40	0.23		
Complete cases (<i>n</i> =174)				7.84***	10.04***
Usual care	2.1 (0.6)	2.2 (0.6)	2.2 (0.6)		
¡Viva Bien!	2.1 (0.7)	2.6 (0.7)	2.4 (0.7)		
Effect size		0.57	0.33		

Based on repeated measures MANCOVAs with age and the baseline value of the dependent variable covaried. BMI was covaried in analyses of saturated fat intake and CIRS-measured use of supportive resources. Unadjusted means are presented in the table. Multivariate *F* statistics (the ratio of the model mean square to the error mean square) and significance values derived from MANCOVAs are provided for the treatment effect (condition *F* value; degree of freedom=1) and for the treatment effect over time (condition by time *F* value; degree of freedom=1). The larger and more significant the *F* statistic, the more likely the intervention produced effects across time

*
p < 0.05;
**
p < 0.01;

p < 0.001

Table 4

Biological and quality of life outcomes at 6 and 12 months

	Baseline <i>M</i> (SD)	6 months <i>M</i> (SD)	12 months <i>M</i> (SD)	Condition <i>F</i> value	Condition by time <i>F</i> value
Hemoglobin A1c (%)					
Intention to treat (<i>n</i> =271)				6.35*	7.65**
Usual care	8.2 (1.7)	8.3 (1.6)	8.3 (1.6)		
¡ Viva Bien!	8.4 (1.9)	7.9 (1.7)	8.3 (1.9)		
Effect size		0.40	0.13		
Complete cases (<i>n</i> =156)				0.12	8.65**
Usual care	8.0 (1.6)	8.1 (1.7)	8.0 (1.3)		
¡ Viva Bien!	8.5 (1.9)	7.7 (1.6)	8.2 (1.9)		
Effect size		0.48	0.14		
Physical health (no. of days not good)					
Intention to treat (<i>n</i> =274)				2.97	2.03
Usual care	7.6 (9.9)	7.5 (9.7)	8.1 (9.2)		
¡ Viva Bien!	8.3 (10.0)	7.3 (9.8)	6.1 (8.4)		
Effect size		0.08	0.23		
Complete cases (<i>n</i> =162)				1.61	2.15
Usual care	5.6 (9.1)	6.4 (9.4)	7.5 (9.0)		
¡ Viva Bien!	7.8 (9.9)	6.8 (9.1)	5.4 (7.9)		
Effect size		0.22	0.40		
Mental health (no. of days not good)					
Intention to treat (<i>n</i> =275)				1.98	.23
Usual care	6.9 (9.2)	7.4 (10.0)	7.3 (9.5)		
¡ Viva Bien!	8.4 (10.1)	6.7 (9.5)	7.3 (8.7)		
Effect size		0.21	0.15		
Complete cases (<i>n</i> =166)				2.02	0.11
Usual care	6.4 (9.4)	7.3 (9.8)	7.4 (9.3)		
¡ Viva Bien!	6.2 (8.2)	6.3 (8.7)	5.9 (8.2)		
Effect size		0.25	0.19		
UKPDS CHD 10-year risk score					

	Baseline <i>M</i> (SD)	6 months <i>M</i> (SD)	12 months <i>M</i> (SD)	Condition <i>F</i> value	Condition by time <i>F</i> value
Intention to treat (<i>n</i> = 261)				4.61 *	2.30
Usual care	10.4 (6.6)	11.5 (7.9)	12.1 (9.3)		
¡ Viva Bien!	10.2 (7.1)	9.1 (6.5)	10.5 (7.7)		
Effect size		0.34	0.18		
Complete cases (<i>n</i> =114)				0.08	6.73 *
Usual care	12.2 (6.9)	11.8 (8.4)	11.0 (7.7)		
¡ Viva Bien!	11.5 (8.2)	10.4 (7.1)	11.7 (9.2)		
Effect size		0.23	0.06		

Based on repeated measures MANCOVAs with age and the baseline value of the dependent variable covaried. BMI was covaried in analyses of hemoglobin A1c. Unadjusted means are presented in the table. Multivariate *F* statistics (the ratio of the model mean square to the error mean square) and significance values derived from MANCOVAs are provided for the treatment effect (condition *F* value; degree of freedom=1) and for the treatment effect over time (condition by time *F* value; degree of freedom=1). The larger and more significant the *F* statistic, the more likely the intervention produced effects across time

*
p < 0.05;
**
p < 0.01;

p < 0.001

Table 5

Partial correlations between change in three sets of outcomes (psychosocial, behavioral, and biological/quality of life)

	6 months	12 months	6 months	12 months	6 months	12 months	6 months	12 months
Psychosocial variables with behavioral variables								
Change in problem solving	0.22*	0.07	0.00	0.00	0.01	0.20*	0.34*	0.11
Change in self-efficacy	0.25*	0.18*	0.13	0.16*	0.15*	0.02	0.22*	0.27*
Change in UCLA score	0.17*	0.09	0.16*	0.30*	0.18*	0.08	0.35*	0.33*
Behavioral variables with biological/quality of life variables								
Change in saturated fat	0.28*	-0.01	0.00	0.10	-0.07	0.00	0.16	-0.10
Change in stress management	0.12	0.25*	0.00	0.01	0.13	0.07	0.09	0.13
Change in physical activity	0.10	-0.09	0.03	0.01	0.07	0.00	-0.03	-0.11
Change in illness resources	0.22*	0.05	0.17*	0.14	0.06	0.06	0.06	0.06
Psychosocial variables with biological/quality of life variables								
Change in problem solving	-0.02	-0.08	0.02	-0.07	-0.15	-0.02	0.11	-0.11
Change in self-efficacy	0.06	0.15	0.08	0.19*	0.06	0.08	-0.02	-0.01
Change in UCLA score	0.18*	0.22*	0.04	0.08	0.00	-0.03	0.07	0.03

Partial correlation coefficients with age and change in BMI partialled out. Change is calculated as a difference score between baseline and follow-up so that positive change indicates improved behavior

* $p < 0.05$