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Community clinic-based lifestyle change for prevention of metabolic syndrome: Rationale, design and methods of the 'Vida Sana/healthy life' program

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A B S T R A C T

Purpose: and Objectives: The risk of diseases associated with Metabolic Syndrome (MetS) is higher for Hispanics living in the northeastern United States than for other racial and ethnic groups. Higher risk of diabetes, high blood lipids, obesity and limited access to continuity of care are all factors that also contribute to disproportionately poorer chronic disease outcomes for Hispanics.
Intervention approach: This article describes the planning and implementation of, and evaluation plans for the Vida Sana Program (VSP), a community-based group intervention created to address the identified MetS risks by encouraging healthier diet and physical activity behaviors among a low-income, largely Spanish speaking, and literacy limited uninsured population. Developed in response to recent calls for culturally-tailored interventions, VSP is conducted by trained bicultural/bilingual *Navegantes*, who deliver a culturally sensitive, fun and engaging eight-week, in-person educational series through group meetings. The intervention also includes a 40-page colorful, picture and graphic enhanced booklet to be used in the group setting and at home. The intervention focused on screening for MetS-associated disease risk factors, understanding chronic disease management, encouraging medication adherence, increasing physical activity, and healthful dietary changes such as limiting alcohol, sodium, unhealthy fats and excess carbohydrate intake, while emphasizing portion control, whole grains and healthy fats.
Conclusions: This creative, community-based approach fills an important gap in the community and in the public health literature, is well liked by health literacy limited patients, and will provide an important model of successfully engaging the Hispanic community on these important health issues.

1. Introduction

Northeastern US Hispanic populations are at higher risk of behavioral and metabolic risk factors and lower access to health screening and care than other groups [1]. Community-based interventions inform and engage community members at risk for metabolic syndrome associated diseases about simple ways to manage their diseases and modify their diet and exercise regimens, which may result in lower risks of morbidity and costs of care.

The Hispanic population in the US represents a variety of cultures, birth places and levels of socioeconomic status. Still, higher behavioral and metabolic risk factors are found for the group as a whole. Hispanic populations in the United States are at higher risk for cardiovascular disease [2] and diabetes due to the prevalence of metabolic syndrome risk factors in the population [3]. For example, Hispanic populations had higher risk of hypertension, diabetes, obesity, and had higher mean total cholesterol, and triglycerides and lower mean HDL levels compared to non-Hispanic White populations (NHW) [2]. The higher prevalence of diabetes among Hispanics compared with NHW is made more problematic by the fact that as much as 40% of diabetes among this group is undiagnosed [3].

Metabolic syndrome (MetS) is a condition combining hyperglycemia/insulin resistance, obesity and dyslipidemia [4]. Hispanics are the highest risk racial/ethnic group in the US for developing metabolic syndrome.[5,6]Among MetS criteria in 2007–2012 data, Mexican American women have higher risk of high waist circumference, lower HDL and higher fasting blood glucose compared with NHW women; while Mexican American men have higher risk of fasting blood glucose

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compared with NHW men [6]. In the northeast, Hispanic women are at higher risk of Diabetes and MetS z score compared to NHW women [1]. The prevalence of MetS rose approximately 35% from 1988 to 1994 to 2007–2012 among adults living in the United States [6]. More than a third of the population of US adults met the clinical criteria for MetS in 2012, indicating increasing risk for several chronic diseases such as type II diabetes, obesity and cardiovascular disease [6].

Behavioral risk factors are inconsistent for US Hispanics. Overall smoking and alcohol consumption are lower, but sedentary behaviors and physically inactive are higher than for NHW [7]. Dietary habits of recent Hispanic immigrants are healthier than NHW, but become similar with acculturation [7,8]. Consumption of sugary drinks and low fruit and vegetable consumption contributes to disease risk. More than half (53%) of Hispanics drink sugary soda daily or weekly as compared to about a third (37%) of Non-Hispanic White according to a nationally-representative bilingual survey [9]. Hispanics were also less than half as likely (7%) as Non-Hispanic Whites (18%) to report eating five or more servings of fruits and vegetables on average per day [9].

Clínica Esperanza/Hope Clinic (CEHC), on the west side of Providence, Rhode Island serves a low-income, uninsured, largely Spanish speaking, and literacy limited population. This study documents the methodology and implementation of the Vida Sana Program (VSP), which was developed to increase the engagement of CEHC community members and patients in the prevention and treatment of MetS and related diseases by encouraging healthier lifestyles.

2. Methods

2.1. Overview of VSP

VSP was developed and is provided by CEHC to CEHC patients and to interested community members. Patients of CEHC experience many of the characteristics of MetS and report many of the associated behaviors, which prompted providers to create a supportive, accessible lifestyle intervention to address these risks. VSP is offered at CEHC (during clinic hours) and also at community sites that partner with CEHC (local churches and community centers). VSP intervention was designed to be sensitive to the cultural, social and linguistic factors that affect CEHC patients and those of other similar free clinics, enabling the patients and community members to expand their health literacy (HL) and allow them to take ownership of their own health.

In 2012, collaborators at the Institute for Education on Health and Research (IEHR) worked with CEHC's team of trained Community Health Workers (*Navegantes)* to develop and lead the VS program. The VSP curriculum uses the Thumbs Up™ materials including workbooks and presentation materials created by IEHR, which facilitate learning through simple terminology and vivid imagery, engaging participants in their health through interactive learning. Navegantes create a mutually supportive, engaging environment for participants, through the use of group games and story-telling, while also celebrating accomplishments with certificates. Created to serve the mostly lower health literate and reading literacy limited clinic population, the interactive eight-week course provides participants with information on basic nutritional principles, healthy lifestyle choices, and management of chronic disease, such as Type II Diabetes and Cardiovascular Disease using simple, easy to understand terminology.

2.2. Recruitment of participants and eligibility criteria

Participants in VSP are usually recruited into the program by providers at CEHC, who refer them for enrollment if they have or are at risk for hypertension, elevated blood lipids, high BMI or waist circumference, prediabetes, or elevated fasting blood glucose or Hemoglobin A1C. Risk is determined as of Hispanic ethnicity or having a family history of the condition. Others who may or may not be CEHC patients seek out the VSP after finding out about the program through word-of-mouth from other participants. VSP has also been held at community locations outside of CEHC, where staff members at the host organization recruit participants. In the past, classes have taken place at the nearby Guatemalan Consulate and at local neighborhood elderly centers that serve the Hispanic population and Spanish-speaking churches in Providence.

2.3. Program administration

Funding from various organizations external to CEHC has been procured to cover the approximately $5000 to $7500 cost for a complete (Orientation + 8 Sessions) VSP class for enrollment of 15–20 participants. Costs include personnel salaries and benefits, printing of educational materials, participant incentives, medical supplies, and class refreshments.

VSP provides incentives in the form of gift cards and healthy snacks to motivate participants to attend. Each person is given a $10 gift card for enrolling, another $10 gift card if they complete the eight weeks of the program, and a third $10 gift card if they attend their follow-up appointment at 12 weeks after the start of the program.

To make VSP more accessible for parents of young children, childcare services are provided at the clinic by staff members when necessary, so that participants know their children are safe and cared for while they attend the class without having to pay for costly babysitting services.

3. Intervention

VSP is provided in 2-h group sessions by Navegantes. The groups involve approximately 70% discussion and 30% sharing of information, using Thumbs Up! course materials.

Navegantes are Community Health Workers (CHW) trained to perform various roles within CEHC, as well as to lead VSP classes. *Navegantes* at CEHC have an ongoing relationship with many patients as they provide a source of support in navigating the healthcare system, including screening participants for eligibility for subsidized health insurance or free care programs at the local hospitals, providing interpretation for the medical providers at CEHC and meeting one-on-one with patients to explain their metabolic indicators. The *Navegantes'* bilingual and bicultural community identities coupled with their role aiding patients in the clinical setting provides an excellent foundation for the additional instruction role of *Navegantes* in healthy lifestyle courses, such as VSP. VSP classes, offered in small groups (10–18 participants) in English and Spanish, are designed to develop and sustain healthy social norms and support by integrating teaching, learning and motivation with the social and community setting.

3.1. Recruitment of community health workers

Careful selection of *Navegantes* at CEHC is paramount in interacting effectively with the patient groups. *Navegantes* are chosen to be bilingual and bicultural and for their ability to be comfortable working with members of the community and speaking to a group. To engage community members during initial recruitment of *Navegantes*, the Medical Director at CEHC reached out to local community organizations and healthcare systems with information about the training process and employment opportunities.

3.2. Training of community health workers

Navegante training, beginning in 2010, occurring annually and funded by community businesses, consists of a 10-week intensive program that teaches skills related to health care case management, medical interpretation, lifestyle coaching for VSP and diabetes prevention programs, first aid, CPR and AED use. Training in Medical Interpretation is also provided, free of charge. Upon successful

completion of the program, *Navegantes* receive Navegante Training Completion and Medical Interpreter Training Completion certificates. The *Navegante* training program is completely cost-free to participants; following a period of observational internships at CEHC and at other organizations, the participants are eligible for formal certification as a CHW by the state of Rhode Island after additional experiential learning.

Navegantes who facilitate the VSP sessions receive more extensive training specific to VSP. These trainings include observing sessions held by other *Navegantes,* co-teaching a class with another *Navegante* and leading several sessions under the supervision of the *Navegante* Coordinator. Each of the classes follows a standard VSP curriculum containing specific learning objectives for each session, but each *Navegante* brings an individualized teaching style to make the program unique and engaging for the participants.

3.3. VSP written materials

A “Thumbs Up! - Healthy Living,” 44-page bound packet of materials was developed by the Institute for Education on Health and Research (IEHR) [10] based on evidence-based strategies compiled by the NIH to overcome health literacy limitations. Health Literacy was identified by medical team members at CEHC as a major barrier to improving the health of CEHC patients who had health problems related to MetS [11]. Strategies employed by the IEHR materials include provision of many images with minimal text to facilitate interactive, discussion-based sessions. The colorful graphics illustrate important health indicators such as Hemoglobin A1C and BMI with visuals that are clearer and more accessible to health literacy limited populations than a text-based explanation. Using a “Thumbs Up! ™” approach, readers get a sense of how clinical numbers are assessed and for each, the healthy range to target. As the name implies, Thumbs Up! uses images of an up or down thumb in varying sizes, sometimes configured on a number line in place of numbers to convey healthier and less healthy, as in BMI or cholesterol numbers, or better and worse choices as in among of dietary fat or beverage options (Fig. 1). The complexity of clinical numbers or even less complicated ideas such as exercises and healthy foods are better conveyed when explained with graphics. Actual labels of foods commonly consumed by participants show readers where to find numbers of calories, type of fat and sugar and challenge the reader to compare labels and pick the healthiest option. Pictures of the colorful package labels are provided for many heathier and less healthy options, along with the thumbs up or down to make identifying these options easier. The visuals also include people of various ages and of various skin-tones depicting a range of cultural groups to which participants might identify. These materials have been well-received by participants and *Navegantes*.

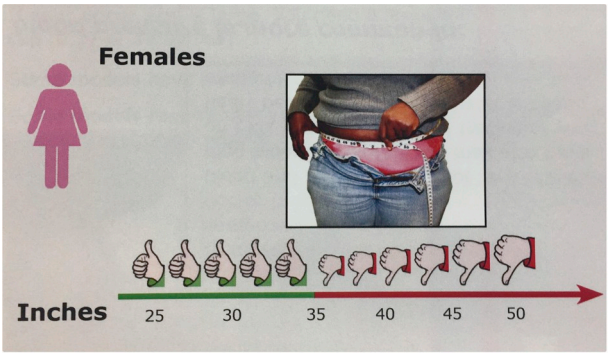

Fig. 1. Vida Sana's visual depictions of healthy and unhealthy numbers in the Thumbs Up! materials.

3.4. Session content

VSP is delivered by *Navegantes* who foster social support among the group while teaching the information in each session (See Table 1). Participants are greeted at each session and asked to sign an attendance sheet before being welcomed to enjoy healthy snacks. As *Navegantes* strive for an enjoyable, social atmosphere that encourages attendance each week, participants are exposed to healthy foods that may be perceived to be unusual, but provide examples of options that could incorporated a healthy diet, and an opportunity to test the snacks without spending money on something new. *Navegantes* begin each session with a review of the information from the previous week, and end each session by asking participants to set health-related goals based on the session content.

During the week, the *Navegante* instructing the next session reaches out to each participant by telephone to remind them of the location, confirm their attendance and reinforce their session content and their personal goals. *Navegantes* chat with participants and encourage participation through this personal connection.

The course begins with an orientation session in which participants have a chance to acquaint themselves with the program and with their classmates. The eight weeks of sessions then begin with conduct of baseline measures of metabolic indicators and knowledge assessment during Session 1. Participants may enter the program as late as Session 3, and initial data collection is scheduled individually for those instances. The full series is conducted over eight sessions that include knowledge and skills related to each topic, motivation to apply the information and skills at home, while addressing likely barriers and fostering social support.

4. Evaluation measures

4.1. Data collection

Measures are collected during Session 1 or the first session attended. The measures include anthropometries, blood chemistries and an assessment of diet, health and wellness knowledge.

4.2. Anthropometry and blood chemistries

The following measures are taken by a *Navegante*/medical assistant overseen by a nurse at weeks 1, 8 and 12 as follows:

- Weight and BMI: Participants are weighed without shoes on a scale dedicated to the VSP. Height is measured at the first evaluation on the stadiometer attached to the dedicated scale, also without shoes. BMI is calculated using these measurements as weight (kg) divided by height (meters) squared.
- Fasting Blood Glucose: Blood glucose testing is conducted using the Assure Platinum 7-Second Blood Glucose Meter [12].
- Hemoglobin A1c: HbA1c testing is done using the Alere Afinion, which offers accurate results from 1.5 μL of finger stick or venous whole blood [13].
- Cholesterol: Fasting cholesterol is tested using the mobile Alere Cholestech LDX [14].
- Blood Pressure: Systolic and diastolic blood pressure measures are taken by trained staff members using a calibrated sphygmomanometer that is dedicated to the VSP. Blood pressure is measured twice, with at least 5 min between measurements. If there is a significant difference between the first two readings, blood pressure is measured again at the end of the session, and this value is used.
- Waist Circumference: A dedicated paper measuring tape is used to measure patients' waist circumference just above the hip bones, at the widest point.

Table 1
Content of Vida Sana sessions.

Session	Topics	Activities
Orientation	Introduction to VSP Benefits and risks of VSP	Ice Breaker
1	Initial "Knowing Your Numbers"	Discussion of metabolic indicators Baseline indicator measurements Statements to consider and form a response: • "I would like to learn …", "Healthy habits that I have are …", • "Unhealthy habits that I have are …" • "My favorite kind of exercise is …" • "My favorite food is …". Set a health goal for the following week. Begin, "Knowing Your Numbers"
2	"Knowing Your Numbers" Diabetes	Discussion of risk factors for pre-diabetes • Model of disease • Risk factors & pre-diabetes • Nutritional modifications • Medications • Monitoring numbers at home Overall discussion of nutrition and weight management for MetS • Understanding nutritional labels • Discussion about how to adjust diet to diabetes or pre-diabetes
3	Comorbidity (Definition) Physical Activity and Exercise Medications	Discussion of exercise and healthy physical activity • Incorporating physical activity into a healthy lifestyle • Differences between moderate and vigorous • Goal setting • Tracking habits Discussion of Medications • Use in MetS and related conditions • Safety • Importance of adherence • Not just taking to feel better • Consistent scheduling • Avoid deviations from prescriptions • What to do if a mistake is made
4	Hypertension Blood Pressure Monitoring Nutrition and Hypertension	Discussion of Hypertension • Definition, diagnosis, complications • Ranges of healthy blood pressure • Self-monitoring process Dietary Modifications • DASH diet • Salt and sodium • Potassium • Finding salt, sodium and potassium on a food label • Cultural considerations when changing diet
5	Hyperlipidemia	Discussion of Hyperlipidemia • Cholesterol and other types of lipids • Blood chemistries Dietary Modifications • Different types of fat: Saturated, polyunsaturated, trans fats • Grocery shopping • Cooking strategies • Oil versus butter • Healthy modifications for cultural favorites • Envisioning dietary change • Responding to family reactions
6 & 7	Reinforce previous sessions Form networks ("Social Clubs")	Review diet modifications and physical activity goals • Play Health Bingo (correct answers correspond with Vida Sana topics) Discuss progress toward goals Discuss practical healthy lifestyle suggestions • Group walking • Buy local produce • Zumba Class (led by Navagante) Cooking demonstration
8	Graduation	Follow-Up Indicator Measures Ceremony of completion (with certificates) Reflection on answers to session 1 questions • Learning goals • Unhealthy foods • Favorite physical activity • Favorite food Consider progress made
1 month after session 8	Follow-Up	Repeat of all measures Follow-up on participants' goals and progress Short review Individual conversation with *Navegantes* about progress and goals Referrals made (if necessary, to other clinicians)

Table 2
Effect size detectable for each.

	Estimated Baseline mean (sd)	200	250	300	350	400
Waist	102.6 (8.9)	1.8	1.6	1.4	1.3	1.2
SBP	126.7 (13.8)	1.8	1.6	1.4	1.3	1.2
DBP	73.5 (9.4)	1.9	1.7	1.5	1.4	1.3
Glucose	105.4 (12.5)	1.8	1.6	1.4	1.3	1.2

4.3. Food and nutrition

Participants complete a pre- and post-intervention assessment to evaluate their improvements in knowledge. The *Navegante* administers the test verbally, using PowerPoint slides with graphics and photos to illustrate the questions. This assessment consists of several tasks: 1) choosing which is the healthier of two food options, 2) classifying blood pressure readings as "healthy" or "unhealthy", and 3) comparing the salt or sugar content of two different foods. Participants record their answers on an answer sheet that features simple graphic responses, such as True or False, A or B, and "thumbs up" or "thumbs down". The *Navegante* repeats the test twice for both the pre- and post-test to ensure that each participant has the opportunity to answer each question regardless of reading or writing ability.

5. Sample size

Though the Vida Sana was not initially created as a research study, the possible sample sizes needed to assess were identified (Table 2). With samples from 200 to 400 participants, differences were calculated based on sample data (means and standard deviations) from an analogous community study [15]. Differences in waist circumference between 1.2 cm (200 participants) to 1.8 cm (400 participants) would be able to be detected. Estimates for SBP, DBP and glucose, the other risk factors for MetS are indicated.

6. Data analysis

A previous manuscript reported data for the pilot year of the VSP intervention at CEHC; showing that 60% of participants had measured improvements in clinical measures at 8 weeks and 90% demonstrated improved health literacy measures, with maintenance of many clinical improvements at later follow-up [16]. Data for years 2–5 presented here will be assessed separately from those previously reported. Baseline values of all clinical measures will be assessed by demographic characteristics using ANOVA models to determine the characteristics of those at higher or lower initial risk. Missing follow-up data will be imputed as the baseline value carried forward. Change in each measure will be assessed as paired t-tests for the overall sample, then separately for groups found to have unhealthy values at baseline. Differences in change by demographics will be assessed with ANOVA models.

7. Discussion

VSP joins other intervention studies that document clinical engagement with Hispanic patients through a community interface [15,17–20]. Similar interventions engage patients in a group format [15,17–20], although a relaxed, "social club," style seems to be unique to VSP. Several other interventions utilized the skills and connection of community health workers [15,18], though the *Navegantes* of VSP combined the training and skill of CHWs with peer counseling. More intensive intervention components, such as home visits [19], and individual level counseling [19], and online counseling [20] have also been included in other intervention studies involving Hispanic populations. Several studies intervened for longer periods of 3–4 months compared with VSP's 8 weeks [19,21], however, promising outcomes do occur even in the shorter format.

VSP, like DPP and others, addresses patients prior to clinical diagnoses of diabetes [15,17–19] or other metabolic syndrome-related conditions [20–23], though many addressed secondary prevention among those being treated [24]. The clinical effects of Hispanic-focused, community-based interventions have also broadened beyond measures associated directly with MetS and associated conditions to assessment of measures of stress [21] or depressive symptoms [19].

Strengths of the VSP study design are in the deep connections with the community. Both the clinical services of CEHC, which ties recruitment to the community through clinical care, and the very personal connection of the *Navegantes* with participants in their teaching style and communication with individual participants throughout underpin the connection of this program to the community. The modest costs mean that this program is feasible to be disseminated to other community clinics, and possibly to other participation groups including other immigrant communities. The metabolic measures collected allow for potential to demonstrate clinical effectiveness. The innovative knowledge data collected using measures designed for literacy limitations also provide indicators of learning processes.

Intervention connections to the community are especially important. Though behavioral risks for Hispanics are clear, these may stem from broader environmental factors. Socioeconomic barriers, lifestyle and relative accessibility to grocery stores stocked with nutritious foods contribute to these disparities [5]. For example, 15.8% of Hispanic families of one study report experiencing food insecurity, which is associated with poor dietary quality and higher rates of obesity overall [25] and among low-income Hispanics [26], though this connection between food insecurity and obesity varies between low-income immigrant groups [27].

In addition to unhealthy behaviors and socioeconomic risk, lack of connection with health care resources may be exacerbated by health literacy limitations, defined by the United States Institute of Medicine, as "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions." [28] Health literacy has been found to be a major barrier to health care within Hispanic immigrant populations in the United States in particular because of the language barriers that exist between patients and their providers. However, even among English-speaking patient populations, it has been estimated that up to 48% do not have adequate functional health literacy [29]. Lower health literacy, which includes skills in understanding complicated vocabulary and numeracy, decreases the likelihood that Hispanics can fully comprehend their health conditions and associated lifestyle factors to allow for healthy behavior change across several lifestyle factors. When health literature is provided only in English, language may also be a barrier to health literacy. Low level reading comprehension among low-income Spanish-speaking populations, even when health education materials are provided in Spanish, may also limit health knowledge acquisition [30].

VSP may be improved by addressing several aspects of the intervention and evaluation aspects of the study. Behavioral theory applied to interventions strengthens the behavioral objectives and targets evaluation to match, but also extends evaluation into the measurement of theoretical psychosocial constructs that would be expected to account for observed behavioral changes. VSP includes many theoretical postulates, but was not planned to intervene on or measure those constructs. Future work might strengthen the connection to behavioral theory to better understand the mechanisms of observed success.

Similarly, the processes by which VSP intervention components are successful should be strengthened, which can more readily occur by strengthening process measures. Robust assessment of the demographics of the patients engaged in VSP in comparison with the CEHC patient population and the characteristics of the broader community would demonstrate how well VSP is reaching or possibly missing groups within the intended target audience. VSP could also be strengthened

with measures of fidelity including adherence to the intervention protocol and dose of intervention received. Measures of consistency among *Navegantes*, quality of the conduct of the program and participant responsiveness would enable VSP to strengthen challenged areas and emphasize those that are already strong. Attendance can be used to address retention, and further to assess the overall dose of the program attained by participants. With stronger measures of dose, we will be able to better identify those who are more or less likely to continue in the program and to target retention efforts toward those groups.

The VSP is an innovative intervention that has been well received in the community and continues to be a successful component of healthcare services provided by CEHC. Future work with VSP will focus on understanding the utility of all components of current structure, as well as possible additional components that might augment the existing format. New applications of the VSP model will identifying how behavioral theory is already being addressed with the current program, and consider strengthening the program utilizing theoretical constructs as the basis. Future enhancement should expand the evaluation plan to include stronger assessment of diet and physical activity behaviors, as well as potential psychosocial mediators of change. VSP is an important contribution to public health research and clinical practice.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2018.10.002.

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