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Evaluation of a culturally-adapted lifestyle intervention to treat elevated cardiometabolic risk of Latino adults in primary care (Vida Sana): A randomized controlled trial

Lisa G. Rosas [a,*], Nan Lv [a], Lan Xiao [a], Megan A. Lewis [b], Patricia Zavella [c], M. Kaye Kramer [d], Veronica Luna [a], Jun Ma [a,e]

[a] Palo Alto Medical Foundation Research Institute, 795 El Camino Real, Ames Building, Palo Alto, CA 94301, United States
[b] RTI International, 3040 Cornwallis Rd., P.O. Box 12194, Research Triangle Park, NC 27709, United States
[c] University of California Santa Cruz, 1156 High Street, Santa Cruz, CA 95064, United States
[d] University of Pittsburgh, 3512 Fifth Avenue, Pittsburgh, PA 15213, United States
[e] University of Illinois at Chicago, Chicago, IL 60607, United States

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ABSTRACT

Latinos bear a disproportionate burden of the dual pandemic of obesity and diabetes. However, successful interventions addressing this disparity through primary care are lacking. To address this gap, the 5-year Vida Sana (Healthy Life) study tests a culturally adapted and technology-enhanced group-based Diabetes Prevention Program intervention in a randomized controlled trial with overweight/obese Latino adults who have metabolic syndrome and/or pre-diabetes. Eligible, consenting patients (n = 186) from a large community-based multispecialty group practice in Northern California will be randomly assigned to receive the culturally-adapted intervention or usual care. The RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework guided the planned evaluations. The primary aim is to determine the effectiveness of the intervention (the "E" in RE-AIM). We hypothesize that the intervention will lead to a greater mean reduction in weight at 24 months (primary endpoint) vs. usual care. Secondary outcomes will include measures of cardiometabolic risk factors (e.g., blood pressure), psychosocial well-being (e.g., health-related quality of life), and behavior change (e.g., physical activity). The secondary aim is to evaluate the other RE-AIM dimensions using mixed methods: reach (e.g., participation rate of the target population), adoption (e.g., participating clinic and provider characteristics), implementation (e.g., intervention fidelity), and maintenance (e.g., sustainability in the practice setting). These findings have real word applicability with value to clinicians, patients, and other decision makers considering effective diabetes prevention programs for primary care that would support the millions of Latino adults who experience a disproportionate burden of diabetes.
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1. Introduction

Ranking as the largest and fastest growing minority group in the United States (US), Latinos reached 55 million in 2014 [1]. The prevalence of overweight and obesity is higher among Latino adults (77%) than non-Hispanic Whites (68%) [2]. Consequently, Latinos have a higher incidence of type 2 diabetes and prevalence of major cardiovascular risk factors (e.g., metabolic syndrome, pre-diabetes) [3–7].

Previous studies have shown that behavioral lifestyle interventions are effective for promoting modest yet clinically significant weight loss and can delay or prevent the onset of diabetes in high-risk adults in community and primary care settings [8–11]. For example, the Diabetes Prevention Program (DPP) trial showed an intensive lifestyle intervention targeting modest weight loss (7%) and increased physical activity (150 min per week) lowered type 2 diabetes incidence by 58% among high-risk, multiethnic adults (55% non-Hispanic Whites, 20% Black, and 16% Hispanic/Latino) [12]. Follow-up data showed that the intervention benefits persisted for at least 10 years [13]. To promote dissemination, the original, resource intensive, primarily one-on-one curriculum was adapted to a group program with fewer sessions, called Group Lifestyle Balance (GLB) [14–16]. The one-year GLB curriculum is approved by the Centers for Disease Control and Prevention through the national Diabetes Prevention Recognition Program [17] and has been proven to be feasible and effective in community and primary care settings [14,18–22].

* Corresponding author.
E-mail addresses: rosasl@pamfri.org (L.G. Rosas), melewis@rti.org (M.A. Lewis), Zavella@ucsc.edu (P. Zavella), mkk3@pitt.edu (M.K. Kramer), maj2015@uic.edu (J. Ma).

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Technology has potential to increase the reach, effectiveness, and scalability of behavioral lifestyle interventions such as the GLB [23–32]. We previously demonstrated the effectiveness of supplementing the GLB 12-session core curriculum with technology-mediated lifestyle coaching via secure email messaging and web-based self-monitoring of weight and physical activity to reduce obesity and cardiometabolic risk factors in a primary care setting in the E-LITE (Evaluation of lifestyle interventions to treat elevated cardiometabolic risk in primary care) study [33–38]. However, similar to other rigorous lifestyle intervention trials in primary care [8,39,40], Latinos were <5% of total participants. Communication technologies (e.g., web, email, mobile) and wearable devices (e.g., pedometers, accelerometers) offer opportunities to tailor interventions to diverse subgroups such as Latinos as well as to promote effectiveness by adapting to individuals' response to interventions over time [41,42].

The primary care setting is ideal given opportunities for primary care physicians to refer at-risk patients, provide on-going management for comorbidities, and support maintenance of preventive lifestyle behaviors. For Latinos, increasing access to healthcare as a result of the Affordable Care Act (for those eligible for insurance or with insurance) [43], makes primary care-based programs increasingly advantageous. Additionally, behavioral lifestyle interventions based in primary care provide an opportunity to provide healthcare for Latinos that is personal, welcoming and concerned for the individual in a social context, which is favored by Latino cultural values [44–46].

To date, few effective and practical behavioral weight-loss interventions that leverage technology and are based in primary care have been developed and tested among high-risk Latinos: a large, vulnerable population with persistent health disparities. To fill this critical gap, the Vida Sana (Healthy Life) study was designed to evaluate a culturally-adapted, technology-enhanced intervention targeting overweight or obese Latino adults with pre-diabetes, a history of gestational diabetes, and/or metabolic syndrome in a community primary care setting.

2. Methods

2.1. Study design

This pragmatic randomized controlled trial (RCT) (11/2014–08/2019) will evaluate a culturally-adapted intervention based on the Group Lifestyle Intervention among high-risk Latino adults. For the purposes of this study, 'Latino' refers to people who self-identify as Latino or Hispanic. The culturally adapted intervention was developed through rigorous formative research and pretesting by a Latino Patient Advisory Board. The specific aims focus on the primary outcome of weight and the evaluation of the domains of the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework: [47]

Aim 1. : Compare the culturally-adapted intervention and usual care for overweight or obese Latino adults with pre-diabetes and/or metabolic syndrome, but without diabetes or cardiovascular disease (the E in RE-AIM).

Hypothesis 1. : Compared with controls, intervention participants will achieve a greater mean reduction in weight from baseline to 24 months (primary outcome).

Hypothesis 2. : Compared with controls, intervention participants will achieve greater improvements in secondary outcomes including measures of cardiometabolic risk factors (e.g., Body Mass Index [BMI], waist circumference, and blood pressure), psychosocial well-being (e.g., health-related quality of life), and lifestyle behaviors (e.g., diet, physical activity).

Aim 2. : Assess intervention attributes in the other RE-AIM domains to gauge generalizability and guide future implementation.

We will use mixed methods to measure other four RE-AIM attributes: Reach, Adoption, Implementation, and Maintenance; and conduct subgroup and effect mediation analyses to explore which patients benefit more and how so.

2.2. Pragmatic RCT

2.2.1. Eligibility criteria

We will apply permissive inclusion criteria and minimally necessary exclusion criteria to optimize the balance between generalizability, patient safety, intervention adherence, and retention. We will enroll Spanish-speaking or bilingual Latino adults ≥18 years with a BMI ≥ 24 kg/m^2 (≥22 if of Asian ancestry) and pre-diabetes [48], a history of gestational diabetes, and/or metabolic syndrome [49], but without type 1 or type 2 diabetes or cardiovascular disease (Table 1) who are active patients at the Palo Alto Medical Foundation (PAMF), a large community-based multispecialty group practice in Northern California. Patients with significant psychiatric (e.g., bipolar and psychotic disorder) or medical comorbidities (e.g., active cancer, organ failure) will be excluded. Additional exclusions are to protect participant safety (e.g., pregnancy) and prevent loss to follow-up (e.g., planned relocation, limited lifespan).

2.2.2. Recruitment and screening

The targeted enrollment of 186 participants will be met in three sequential cohorts of 62 patients each. Each cohort will be recruited from one of three different clinic sites within PAMF where participants randomly assigned to the intervention group will attend the group sessions. Recruitment and screening will proceed in four steps. First, PAMF patient Electronic Health Records (EHRs) will be pre-screened to identify potential participants meeting basic eligibility criteria (e.g., age, active patient status, and absence of exclusionary medical or psychiatric comorbidities). Second, Primary Care Physicians (PCPs) at each site will review lists of potentially eligible patients, exclude those they deem inappropriate for the study because of medical reasons, and authorize study contact for the rest. Third, PCP-approved patients will receive a recruitment email or letter in Spanish and English introducing the study and inviting them to complete an initial brief screening online, which focuses on those eligibility criteria that individuals can reliably assess themselves (e.g., pregnancy, likelihood of relocation). Two weeks after sending the email or letter, recruitment staff will phone patients who have not done self-screening and who did not opt out, to complete the initial screening. Fourth, patients who screen eligible will complete an in-person baseline visit at the clinic site from which they were recruited. Patients will receive the link to a self-administered survey for completion prior to the in-person visit so as to reduce the overall time of the visit. If patients cannot or do not want to complete the survey prior to the visit, they can do so at the visit. The visit will begin with obtaining written informed consent. A trained bilingual research assistant will orally administer the baseline questionnaire and conduct standardized height, weight, waist circumference, and blood pressure measurements [50–52].

2.2.3. Randomization and blinding

Eligible participants will be randomized in a 1:1 ratio to receive usual care or usual care plus the intervention (n = 93/arm). We will apply a covariate-adaptive biased coin method that we have published [53] and used successfully in several trials [54,55] to achieve good marginal balance between treatments across the following baseline characteristics: clinic, age, sex, BMI, waist circumference, and level of acculturation assessed by the Short Acculturation Scale for Hispanics [56,57]. The dynamic block randomization algorithm of our method automatically ensures allocation concealment. By design, treatment will be identifiable to participants and the lifestyle coach, but masking of the investigators, Data and Safety Monitoring Board, outcome assessors, and data analyst will be enforced. The bilingual and bicultural lifestyle

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