

REVIEW

Transculturalizing Diabetes Prevention in Latin America



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Abstract

BACKGROUND Type 2 diabetes (T2D) imposes a heavy burden in developing countries, requiring effective primary prevention policies. Randomized clinical trials have identified successful strategies in T2D prevention. However, translating these results to real-life scenarios and adapting to ethnocultural differences is a major challenge. Transculturalization allows incorporating cultural factors to diabetes prevention strategies to optimize implementation of clinical trials results. The purpose of this paper is to review the transcultural adaptations developed for T2D prevention in Latin America (LA).

METHODS A comprehensive literature review spanning 1960-2016 was performed, using “Diabetes,” “Latin America,” “Prevention,” “Screening,” and “Tools” as key words.

RESULTS Two major tasks are underway in LA: adaptation of screening tools for high-risk individuals, and implementation of diabetes prevention programs. The Finnish Diabetes Risk Score (FINDRISC) is the most widely used screening tool to detect new cases of T2D and people with prediabetes, and it has been adapted (LA-FINDRISC) to include the waist circumference cutoff values appropriate for LA population (≥ 94 cm for men and ≥ 90 cm for women). The validation of the LA-FINDRISC performance depends on the local characteristics. A LA-FINDRISC score >10 may be the best cutoff to identify individuals with impaired glucose regulation in population-based studies, but a higher score ($>12-14$) might be more appropriate in a clinical setting. A shorter version of the FINDRISC using only the 4 variables with highest impact has been developed and validated in Colombia (CoDRISC). The translation of the Diabetes Prevention Program study in a Latino population in Venezuela found a significant improvement in cardiometabolic risk factors. An adaptation of the Diabetes Prevention Study in the DEMOJUAN study in Barranquilla, Colombia, reduced 2-hour postload glucose.

CONCLUSION Successful transculturalization strategies have been implemented in screening tools and prevention programs in LA.

KEY WORDS FINDRISC, Latin America, prevention, type 2 diabetes, validation.

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INTRODUCTION

The Global Dimension of Diabetes Prevention. Type 2 diabetes (T2D) and its complications impose a heavy burden on public health systems worldwide.^{1,2} In 2013, T2D represented the 12th leading cause of disability-adjusted life years³ and the 17th leading cause of death globally.⁴ The worldwide prevalence of diabetes in the adult population was 415 million (8.8%) in 2015 and predicted to rise to 642 million (10.4%) by 2040.⁵ In Latin America (LA), the International Diabetes Federation estimated that 9.4% adults had diabetes and 7.9% had impaired fasting blood glucose (IFG) in 2015, and these numbers are expected to rise to 11.9% and 9.4%, respectively, in 2040.⁵ In the South and Central America region, 24% of adults with diabetes are undiagnosed, extending to 50% in some countries.⁶

The main drivers of T2D prevention appear to be weight loss and increased physical activity,⁷ and therefore these interventions must be included in effective prevention strategies to reduce the burden of T2D.² Prospective studies have found that T2D can be prevented by early intervention in people with IFG and/or impaired glucose tolerance (IGT).^{8–12} However, translating results from controlled clinical trials to real-life scenarios represents a major challenge, particularly when adapting ethnocultural differences.¹³ *Transculturalization* describes the process of adapting concepts from one culture to another, without changing either culture.¹⁴ In other words, transculturalization in diabetes prevention involves the incorporation of cultural factors to optimize implementation of a scientific template for diabetes prevention.¹⁵

A recent systematic literature review pointed out that screening for T2D and IGT, with appropriate intervention for those with IGT, seems to be cost effective.¹⁶ However, the cost effectiveness of a policy of screening for T2D alone, without offering an intervention to those with IGT, is still unclear. A number of risk-scoring models have been developed^{17–19} for screening, even though some of them are limited by the need of laboratory tests. Recently, a study validating existing non-laboratory-based models and assessing the variability in predictive performance in European populations found that existing diabetes prediction models can be used to identify individuals at high risk of T2D in the general population.²⁰ The Finnish Diabetes Risk Score (FINDRISC) is the most widely used tool because of its simplicity, affordability, and reliability.²¹ Nevertheless, validation of these tools as part of the

transculturalization process is still needed.²² This review summarizes the key LA studies evaluating screening tools that are culturally adapted to the region, as well as the strategies that have been successfully implemented for diabetes prevention.

METHODS

The purpose of this paper is to provide a review of the adaptations developed for T2D prevention in LA, focused on screening tools and the translation of diabetes prevention programs. Because of the limited evidence published on this topic, we were unable to perform a systematic review. Instead, a comprehensive literature review spanning 1960–2016 was performed, using “Diabetes,” “Latin America,” “Prevention,” “Screening,” and “Tools” as key words. This review also contains original data from the authors only previously published in posters.

RESULTS

Strategies of Transculturalization in Diabetes Prevention.

Transcultural Initiatives in Latin America. Transculturalization incorporate ethnocultural factors to optimize implementation of an evidence-based template, and in this case, for diabetes prevention and care.¹⁵ The clinical practice algorithm (CPA) has emerged as the ideal format to convey recommendations and is based on validated transculturation protocols.²³ The CPA is a derivative of related clinical practice guidelines. After transcultural adaptation, the CPA is then implemented, evaluated according to prespecified outcome metrics, and then optimized for a specific target population.²³ A stepwise approach to transculturalization process presented in an algorithmic format, including validated protocols and frameworks for cultural adaptation, has been proposed.²⁴

The transculturalization experience in LA has already been initialized. For example, after comparing measurements of visceral adipose tissue obtained by computerized axial tomography with abdominal circumference in participants from 5 LA countries, it was proposed that the cutoff point to identify people with abdominal obesity is ≥ 94 cm in men and ≥ 90 cm in women, which differs from other ethnic groups.²⁵ In a US population it was estimated that a cutoff of body mass index (BMI) > 30 kg/m² underestimates the proportion of participants with excess body fat in the obese range as measured by bioimpedance.²⁶

Similar findings in Venezuelan people indicated that a cutoff of 27.5 kg/m² appears to identify more participants with excess body fat in the range of obesity.²⁷

Nutrition (including medical nutrition therapy) and physical activity recommendations, not to mention their transculturalizations, receive relatively little attention in diabetes clinical practice guidelines. This shortcoming has been addressed by the development of the transcultural Diabetes Nutrition Algorithm (tDNA).²⁸ An evidence-based algorithmic template of diabetes care was produced in 2012,²⁸ followed by transcultural adaptations from 7 countries and regions, including Venezuela,²⁹ Brazil,³⁰ and Mexico,³¹ and then comprehensive tDNA reviews.^{14,24} Each country or region has unique epidemiological, cultural, physiological, ethnic, nutritional, pathologic, and lifestyle characteristics, as well as distinct political, economic, and social environments. For example, an adaptation of the Mediterranean pyramid using local foods and culinary techniques was proposed in the Venezuelan version.^{29,32}

In a recent initiative of transculturalization in LA, the American Association of Clinical Endocrinologists and the American College of Endocrinology standardized a methodology to guide local development of CPA in endocrinology, specifically in diabetes, obesity, thyroid nodule, and osteoporosis.¹⁵ Although they do not recommend universal screening for diabetes and prefer aggressive case finding, they suggest to provide the epidemiological data supporting that the LA population is at high risk for T2D, which might justify the former. These transcultural initiatives in LA should be followed by evaluations of their implementability, endpoints, and effectiveness.²⁴

Detection of Participants at Risk of Diabetes in Latin America. The aim of detecting people at risk of T2D should be to identify those who can benefit from prevention strategies—that is, people with IGT, with or without IFG. The oral glucose tolerance test (OGTT) is the gold standard for the diagnosis of IGT, but it is impractical for screening, especially at the population level. Abnormal fasting blood glucose (FBG) may identify a large proportion of those participants and FBG could be used as a sensitive screening test,³³ but it is still invasive (venipuncture or at least fingerstick), requires fasting, and needs special equipment. Therefore, diabetes risk scores using clinical data and no laboratory tests have emerged as practical screening tools to screen for people at high risk in the general population.³⁴

A proper risk score accurately predicts individuals at risk (calibration); distinguishes reliably between

a high-risk population and low-risk people (discrimination); and performs well in other populations (generalizability).³⁴ But a risk model or score should not be extrapolated to a different population without a transcultural validation and implementation process. Validating a risk score means testing its calibration (weighting the different elements of the score according to local data) and discrimination either internally (by splitting the original sample, developing the score on one part and testing it on another), temporally (rerunning the score on the same or a similar sample after a period), or externally (running the score on a new population with similar but not identical characteristics from the one on which it was developed).^{35,36}

Participants with impaired glucose regulation (IGR), which include those with IFG or IGT, and participants with unknown diabetes (uDM) can be identified by risk scores. Although they will need a diagnostic test either using blood glucose or glycosylated hemoglobin (HbA1c), screening by using a risk score such as FINDRISC is cost effective, as indicated by recent analysis in Colombia.³⁷ In this analysis, the most cost-effective strategy to screen for diabetes was using FINDRISC, followed by FBG and OGTT if necessary.³⁸ Although the evidence supports the screening of individuals with intermediate hyperglycemia (ie, prediabetes), it is not incorporated in the institutional screening strategies in LA.³⁸

In a systematic review reporting 94 risk models, of which 39 were external validations, only 1 was a cohort external validation in LA, specifically in Mexico.³⁴ In the development of this score were included 525 participants, aged between 20-65, who were followed up to 7 years. The score included laboratory measurements, which may be considered a disadvantage, as well as a large number of components (11 in total). Fasting plasma glucose (FPG) was the strongest predictor of diabetes, even more than the combination of other risk components.³⁹ Obviously, to include the value of FPG within the model certainly improves the sensitivity (92%) and specificity (71%) to predict future diabetes in this cohort (area under the curve [AUC] in the receiver operating characteristic [ROC]) = 0.91.³⁹ It has to be kept in mind that the objective of the risk scores is to develop a simple tool helping to distinguish whom to apply further blood tests. This initial effort revealed the importance of developing or validating simpler diabetes risk scores in LA.

Validation of Risk Scores in Latin America. The FINDRISC is one of the most efficient and widely used screening tool to detect new cases of T2D.²¹ It

includes anthropometric (BMI and waist circumference), metabolic, and lifestyle factors that predict T2D.²¹ However, the FINDRISC needs to be validated in populations other than the original Finnish population where it was developed,⁹ to determine performance attributes (eg, sensitivity and specificity). Several LA countries have done validation studies using modified versions of the original score (Table 1).⁴⁰⁻⁴⁴

The first modified version of the original FINDRISC (O-FINDRISC) was named Latin America FINDRISC (LA-FINDRISC) and was developed because the waist circumference categories used in the original version were adapted to the definition of abdominal obesity in Europe and in the United States (for men ≥ 94 cm and >102 cm and for women ≥ 80 cm and >88 cm, respectively).⁴⁰ The scores were also categorized accordingly (3 and 4 points, respectively, for both genders). As mentioned before, it has been described that the waist circumference that had the highest sensitivity and specificity to identify people with abdominal obesity in Latin America is ≥ 94 cm for men and ≥ 90 cm for women²⁵; and a score of 4 points in the LA-FINDRISC was assigned, and values less than that scored 0. In the first study of external validation, LA-FINDRISC and O-FINDRISC were compared in a Colombian population recruited by open invitation at the Colombian Diabetes Association in Bogotá and a Venezuelan population selected from an obesity and risk factors clinic in Barquisimeto.⁴⁰ In both populations the LA-FINDRISC had a very good discrimination power to identify people with IGR (IFG, IGT, uDM). The AUC-ROC of the LA-FINDRISC was similar to the O-FINDRISC in men but was significantly greater in women. A score >12 points in Bogotá and >14 points in Barquisimeto had the best sensitivity/specificity ratio to screen participants with IGR who would be eligible for blood glucose testing.⁴⁰ The performance of the LA-FINDRISC was also tested in two primary care centers in Uruguay, where the AUC was also similarly good and the Youden index indicated the best cutoff at a score >14 .⁴¹

Because the LA-FINDRISC may perform differently in a population-based study, it was tested in a random sample of 521 participants recruited for the EVESCAM (Venezuelan Study of Cardio-metabolic Health).⁴² EVESCAM is a national cross-sectional and cluster sampling study designed to evaluate the prevalence of diabetes and cardiometabolic risk factors and their relationship with lifestyle in Venezuela and is expected to recruit 4200 participants.⁴⁵ The dis-

crimination power to detect IGR was significant (AUC 0.68, 95% confidence interval [CI] 0.64-0.72, $P < .0001$), and the score at which the discrimination performed best was >10 , with a sensitivity and a specificity of 63.4% and 61.2%, respectively. This cutoff is comparable with other population studies (Table 2).^{46,47}

As shown in these examples, the performance of the risk score will vary from one population to the other, and the best cutoff score to screen may depend on the characteristics of the population. For example, the cutoff may be higher in participants with more risk factors, as found in Barquisimeto where people were more obese. Besides, the use of LA-FINDRISC cutoffs derived from patients or captive populations to screen the general population may underestimate the number of participants who need OGTT to detect IGR. The selection of the cutoff may also depend on the purpose of the screening: If it is performed to select candidates for a community diabetes prevention program, then high sensitivity may be preferred and the cutoff can be lower. On the contrary, if the prevention program is limited and it is desirable to select patients at the highest risk who will benefit most, then high specificity may be preferred and the cutoff can be higher. The yield of positive versus negative diagnostic tests will vary accordingly.

The LA-FINDRISC has also been simplified to include only the risk factors that have the highest predictive weight. This risk score was developed in Colombia (ColDRISC) and resulted from a cross-sectional study of 2060 participants aged 18-74 years, from a population insured by a health care company in northern Colombia.⁴³ The variables that remained independent in the logistic regression were age, waist circumference (using the LA cutoffs), use of antihypertensive medication, and family history of diabetes. The power to identify people with IGR by the ColDRISC was similar to the O-FINDRISC and the LA-FINDRISC (AUC-ROC 0.74, 0.73, and 0.73, respectively) and a cutoff score ≥ 4 was the best tradeoff between sensitivity and specificity.⁴³ With exception of the ColDRISC, none of the other FINDRISC validation study did assess the weight of the different elements of the risk scores. However, although this risk score may be shorter, the missing variables could have given the opportunity to explore and educate about lifestyle (nutrition and physical activity), as well as important information on BMI. Also, the results from the ColDRISC cannot be compared with other studies using the full FINDRISC.

A recent version of the FINDRISC with a different adjustment of the waist circumference cutoff

Table 1. Validation of FINDRISC in Latin America to Identify People With Unknown Diabetes and With Impaired Glucose Regulation (IFG and/or IGT)

Risk Score	Country/Year/Author	Population setting	n	Diagnostic test	Aim	Sensitivity/Specificity (%)	AUC-ROC	Cutoff to detect IGR
Original FINDRISC	Finland/2003/Lindstrom and Tuomilehto ^{9,21}	General	4435	OGTT	Determine if T2D can be prevented by lifestyle interventions in participants at high risk for the disease	Cohort (1987) 78/81 Cohort (1992) 77/76	Cohort (1987) 0.85 Cohort (1992) 0.87	≥9
LA-FINDRISC	Colombia/2012/Aschner et al ⁴⁰	General	421	OGTT	Compare O-FINDRISC with LA-FINDRISC	Men 74/60; Women 77/67	Men 0.77; Women 0.78	>12
	Venezuela/2012/Aschner et al ⁴⁰	Clinical	334	OGTT	Compare O-FINDRISC with LA-FINDRISC	Men 97/70; Women 91/78	Men 0.91; Women: 0.92	>14
	Uruguay/2015/Vignoli et al ⁴¹	Clinical	109	OGTT	Evaluate LA-FINDRISC	70/66	Overall 0.74	>14
	Venezuela/2015/Nieto-Martínez et al ⁴²	General Population	521	OGTT	Evaluate LA-FINDRISC	63/61	Men 0.71; Women 0.67; Total 0.68	>10
CoDRISC	Colombia/2015/Barengo et al ⁴³	Captive (insurance company)	2060	OGTT	Develop and compare CoDRISC with LA-FINDRISC	CoDRISC 73/67 LA-FINDRISC 72/60	CoDRISC 0.74 LA-FINDRISC 0.73	CoDRISC >4*
Modified FINDRISC	Colombia/2015/Gomez-Arbelaiz et al ⁴⁴	Clinical	772	A1c	To evaluate the performance of FINDRISC detecting and predicting T2D	Men 66/75; Women 71/62	Men 0.74; Women 0.71	>14

Modified FINDRISC includes a modification in the waist circumference cutoff values: Men: <90 cm (0 risk points); 90-98 cm (3 risk points); >98 cm (4 risk points). Women: <80 cm, (0 risk points); 80-88 cm (3 risk points); >88 cm (4 risk points). AUC, area under the curve; CoDRISC, Colombian Diabetes Risk Score; IFG, impaired fasting blood glucose; IGR, impaired glucose regulation; IGT, impaired glucose tolerance; LA-FINDRISC, Latin America FINDRISC; O-FINDRISC, Original Finnish Diabetes Risk Score; ROC, receiver operating characteristic; T2D, type 2 diabetes.

* Not comparable with other FINDRISC versions.

Table 2. AUC in ROC and Cutoff to Detect IGR in Population-Based Studies

Variable	n	Age (yr)	AUC-ROC			Sensitivity (%)			Cutoff			
			Men	Women	Total	Men	Women	Total	Men	Women	Total	
Venezuela ⁴²	IFG/IGT/uDM	521	≥20	0.71	0.67	0.68	58.6	62.0	63.4	10*	10*	10*
Finland ⁴⁶	IFG/IGT	2966	45-74	0.65	0.66	NA	45.6	53.4	NA	11†	11†	NA
Finland ⁴⁶	uDM	2966	45-74	0.72	0.73	NA	66.1	70.0	NA	11†	11†	NA
USA ⁴⁷	IFG/IGT	20,633	≥20	0.66	0.70 [§]	0.67	60.9	68.7	NA	9 [‡]	10 [‡]	NA
USA ⁴⁷	uDM	20,633	≥20	0.74	0.78 [§]	0.75	74.7	72.2	NA	10 [‡]	12 [‡]	NA
USA Hispanic ⁴⁷	IFG/IGT	5138	≥20	NA	NA	0.65	NA	NA	55.9	NA	NA	10 [‡]
USA Hispanic ⁴⁷	uDM	5138	≥20	NA	NA	0.7 [¶]	NA	NA	66.0	NA	NA	11 [‡]

AUC-ROC, area under the receiver operating characteristics curve; IFG, impaired fasting blood glucose; IGR, impaired glucose resistance; IGT, impaired glucose tolerance; NA, not available; uDM, unknown diabetes.
 Criteria for optimal cut point: *Youden index (J) and sum sensitivity + specificity favoring sensitivity; †Sensitivity, false-positive rate. PPV (not described in detail). ‡Upper confidence limit distance: Shortest distance in the ROC curve (square root of [(1-sensitivity)² + (1-specificity)²]).
[§] Significant difference by gender.
^{||} Lower in Hispanic (AUC 0.72) versus white (AUC 0.76); P = .03.
[¶] Lower in Hispanic (AUC 0.65) versus white (AUC 0.68); P < .001.

points that confer an increased cardiometabolic risk in the Colombian population (90-98 cm scored 3 points and >98 cm scored 4 points in men; similarly 80-88 cm scored 3 and >88 cm scored 4 in women; lower values scored 0) was tested in a prospective study in a clinical setting in Floridablanca, Colombia.⁴⁴ A cutoff score ≥14 points identified undiagnosed T2D, and ≥13 points in men and ≥16 in women predicted incident T2D in the subsample of prediabetic participants. This study confirmed the utility of FINDRISC to detect uDM and was the first in LA to validate FINDRISC to predict incident T2D among prediabetics.⁴⁴ However, as mentioned before, the extrapolation of a cutoff obtained from patients to the general population could be erroneous.

Although population screening for T2D does not meet all the criteria of the UK National Screening Committee, this committee recommended use of the available risk scores (QDiabetes Risk Score or FINDRISC) to define participants requiring blood tests (FPG, OGTT) to diagnose prediabetes or uDM.⁴⁸ The recommendation of validating and applying the FINDRISC for screening has been proposed for Venezuela in the tDNA²⁹ and was also endorsed for LA by a group of LA experts.⁴⁹ Validating the different components of the FINDRISC within the LA population is an important task in the near future because the optimal scores for each item of the FINDRISC vary in each population.⁵⁰

Despite the recommendations, in most Latin American countries institutional screening programs for early detection of T2D have not been established.³⁸ Self-assessment websites have been implemented to increase education about the risk of

developing T2D. The Spanish Foundation of Diabetes proposed an Internet-based Spanish version of the e-FINDRISC.⁵¹ During the first year, 23% of e-FINDRISC screenings were completed by LA people, mainly from Mexico (33.6%), Argentina (25.6%), Venezuela (6.8%), Colombia (6.7%), Chile (6.1%), and Peru (5.8%),³⁸ detecting 20.8% of individuals as at high risk for developing T2D.³⁸

Laboratory Tests. Biochemical tests (eg, FPG, OGTT, and HbA1c) are the recommended tools to diagnose prediabetes and diabetes but are not always available or reliable. Technical errors are found in LA countries—for example, the use of a postbreakfast blood glucose instead of OGTT, and the lack of standardization of HbA1c in all laboratories.²⁸ The 2015 Pan-American Workshop Transculturalization Recommendations for Developing Latin American Clinical Practice¹⁵ recommended aggressive case finding to identify those most likely to have the disease, to obtain the major benefit from treatment, and avoid “universal screening.”

Interventions in Participants at Risk of Diabetes in Latin America.

Diabetes Prevention Program-Based Strategies. Randomized clinical trials in the United States (Diabetes Prevention Program [DPP]),⁸ Finland (Diabetes Prevention Study [DPS]),⁹ China (DaQing),¹⁰ and India (Indian DPP)¹² using structured interventions in participants at high risk for T2D found that lifestyle changes can prevent or delay the development of T2D. The initial reports in Finland and the United States found reductions of 58% in the risk of T2D.^{8,9} The long-term follow-ups in these studies have shown durable effects in the Chinese study at 20 years (43%),⁵² in the US study at 10 years (34%),⁵³

and the Finnish study at 7 years (36%).⁵⁴ Despite their efficacy, the obvious challenge is to translate these study interventions into routine clinical practice for different settings.

Some studies have translated DPP strategies for Latino populations (Table 3).⁵⁵⁻⁶⁰ All these studies⁵⁵ have reported effectiveness, implementation strategies or other factors related with implementation, and cultural adaptations, but only 2 were randomized clinical trials.^{56,57} Florez *et al.*⁵⁷ implemented a clinic-based intensive lifestyle intervention, culturally adapting the DPP core program, in 140 participants with prediabetes (63.6% women, 48.1 ± 11.8 years old and 32.1 ± 5.5 kg/m²) from Maracaibo, Venezuela, who were randomly assigned to receive either standard of care (SC group; N = 70) or lifestyle intervention (ILS group; N = 70) for 2 years. At 6 months, the Framingham Diabetes Risk Score and its components were reduced significantly in the intervention group, associated with a higher weight loss (BMI -1.9 kg/m² vs 0.4 kg/m², $P < .001$; intensive vs standard, respectively), reduction of fasting blood glucose (-10.2 mg/dL vs 1.82 mg/dL; $P < .001$; ILS vs SC, respectively), and improvement on lipid profile and diastolic blood pressure.⁶¹ In this study, ideal cardiovascular health behaviors (nonsmoking, achieving normal weight, enough physical activity, and a healthy diet) and health factors (total cholesterol < 200 mg/dL, blood pressure $< 120/80$ mm Hg, and fasting blood glucose < 100 mg/dL) were evaluated at baseline and every 6 months for 2 years. The American Heart Association global cardiovascular health score assigning 1 point to each ideal behavior and factor (for a maximum of 7 points) and 0 points for poor status to each behavior/factor was calculated. The cardiovascular score at baseline was 3.9 ± 0.1 (84.3% in SC and 88.6% in ILS had poor to intermediate cardiovascular scores). Larger improvements in the cardiovascular scores from baseline were obtained in the ILS versus SC (2.0 ± 0.9 vs 0.8 ± 0.6 ; $P < .0001$) groups at 24 months of intervention.⁵⁷ At study end, only 4.3% of ILS and 47.1% of SC participants had poor to intermediate cardiovascular scores ($P < .01$).⁵⁷ This study concluded that the implementation of DPP-based lifestyle intervention to reduce diabetes risk in the clinical setting is feasible in Latinos in developing countries and achieves metabolic benefits comparable to those observed in major clinical trials.⁵⁷

Considering that acculturation (changes in culture that occur when 2 or more cultures interact) of Latino population in the United States increases the risk for cardiovascular disease and T2D,⁶² it is important to explore the implementation of diabetes prevention

in the largest minority group in United States. Ockene *et al.*,⁵⁶ in a randomized clinical trial (Laurence Latino Prevention Project), implemented a low-cost and lower intensity intervention, based on a modified DPP intervention to Latinos, with 3 individual and 13 group sessions over a 12-month period, including 312 Latinos with elevated risk for T2D. After 12 months of participation, reductions in weight (-2.5 vs 0.63 lb; $P = .04$) and HbA1c (-0.10% vs -0.04% ; $P = .009$) were identified compared with the control group, accompanied by an improvement in insulin resistance.

At least 3 single-group prospective intervention studies translating the DPP lifestyle strategies in Latinos have been published.^{55,58} In the Kramer *et al.*⁵⁸ study, bilingual trained health professionals applied a 12- to 15-week diabetes prevention program in 27 Hispanic women at high risk of diabetes to reduce weight. More weight was lost by the group that attended 6 sessions (3.9%) compared with the group attending 3 sessions (2.8%), and the number of sessions attended was positively correlated with weight loss ($P = .01$). Some barriers to attendance were new employment, participants' and children's health problems, and lack of transport.⁵⁸ Ruggiero *et al.*,⁵⁵ in a tailored program delivered by community health workers in a Latino community during 1 year, obtained benefits in weight loss and changes in both eating habits and physical activity, mainly at 6 months. Kutob *et al.*,⁵⁹ combining family support with the group office model, propose group office visits as a new sustainable model for diabetes prevention. In Chile, an integral program on weight reduction in 128 women with overweight or obesity and at high risk for T2D was implemented.⁶³ Intervention included 32 guided physical activity sessions, 8 nutritional sessions, and 7 psychological sessions. After 4 month of intervention, and an observational extension until the sixth month, an improvement in metabolic profile, including a reduction of FBG in 9.2%, but no differences in weight were noted. Some weaknesses of the study were related to a lack of a framework for implementation strategies and the need a proper comparator group.⁶³

A randomized clinical trial adapting DPP strategies in 92 Latinas living in the United States was recently presented by O'Brien *et al.*⁶⁰ Participants received lifestyle intervention (LSI) with 24 sessions delivered by trained community health workers (promotoras) and were compared with metformin use (850 mg twice daily) and SC. After 12 months of follow-up, the LSI group achieved a greater mean weight loss (-4.0 kg, 5.0%) than metformin (-0.9 kg, 1.1%) and SC participants ($+0.8$ kg, 0.9%) ($P < .001$).

Table 3. Translations of the Diabetes Prevention Program in Latino/Hispanic Populations

Country/Year/ Author	Goals/Outcomes	Trial Design/Sample	Program Implemented/Endpoints/ Duration of Intervention	Results
Venezuela/2012/ Florez et al ⁵⁷	Demonstrate the effectiveness of clinic-based LSI modifications on the AHA ideal CHS in a Latino population with prediabetes	Randomized clinical trial/70 participants LSI vs 70 participants SCI/1159 Latinos from Venezuela recruited	US DPP core strategies/evaluating changes in AHA-CHS and metabolic variables/24 mo	Compared with SCI group: LSI improved the global CHS (LSI vs SCI: 2.0 ± 0.9 vs 0.8 ± 0.6 ; $P < .0001$) LSI improved lipid profile and inflammatory biomarkers
USA/2012/Ockene et al ⁵⁶	Test the effectiveness of a community-based lifestyle intervention among Latinos at increased T2D risk	Randomized clinical trial (randomized block design)/lifestyle intervention care (IC) vs usual care (UC)/321 Spanish-speaking Latinos from the United States	Adaptation of the US DPP intervention, literacy sensitive, and culturally tailored, with 3 individual and 13 group sessions/weight loss and T2D risk reduction/12 mo	IC had greater weight loss (-2.5 vs 0.63 lb; $P = .04$) and HbA1c reduction (-0.10% vs -0.04% ; $P = .009$) than UC
USA/2013/Kramer et al ⁵⁸	Evaluate the effectiveness of a Spanish translated version of the Group Lifestyle Balance (GLB) program for diabetes prevention on a high-risk Hispanic population to reduce weight	Single-group prospective intervention study/27 overweight/obese Hispanic women from the Women, Infants and Children (WIC) program	Bilingual GLB-trained health professionals delivered the program with measures collected at baseline and after intervention/weight loss/12-15 wk	Overall mean weight loss: -2.8% for those who attended at least 3 sessions -3.9% for those who attended at least 6 sessions
USA/2014/Kutob et al ⁵⁹	Describe the development and implementation of a new diabetes prevention intervention combining family support with the group office model	Single group prospective intervention study/adults (37.9% Hispanic/Latinos) with any diabetes risk factor/29 pairs (n = 58) of primary participants plus support persons	Twelve family group office visits (Families United/Familias Unidas curriculum) based on DPP and a previously developed group office visit program/weight loss/6 mo	Overall mean weight loss: At the end of intervention (6 m): -2 kg 6 mo after the intervention: -3.2 kg 12 mo after the intervention: -3.4 kg 15% more risk factor reduction in primary participants
USA/2011/Ruggiero et al ⁵⁵	Tailor, enhance, deliver, and evaluate a community-based version of the DPP clinic-based lifestyle intervention in Latino participants	Single-group prospective intervention study/69 Latinos with glucose levels ranging from normal to prediabetes	The Healthy Living Program (HLP) based on the DPP delivered by community health workers/weight loss, eating habits and physical activity/12 mo	At 6 mo: 20% achieved a 7% weight loss goal (16% at 12 mo) Changes in eating habits Changes in measures of physical activity (not maintained at 12 mo)
USA/2017/O'Brien et al ⁶⁰	Compare the real-world effectiveness of adapted Diabetes Prevention Program's intervention among Latinas women with prediabetes	Randomized clinical trial/92 women randomly assigned to LSI vs metformin vs SCI	DPP-based ILI delivered by "promotoras" (community health workers)/weight change/12 mo	Weight change at the end of the study: LSI: -4.0 kg, 5.0% Metformin: -0.9 kg, 1.1% SC: $+0.8$ kg, 0.9% ($P < .001$)

AHA, American Heart Association; BMI, body mass index; CHS, cardiovascular health score; DPP, Diabetes Prevention Program; DPS, Diabetes Prevention study; IC, intervention care; LSI, lifestyle intervention; NR, not reported; SCI, standard of care intervention; UC, usual care.

Table 4. Fasting and 2-hour Glucose Values in OGTT of the DEMOJUAN Participants in 2011 and 2015 According to Participation in the Lifestyle Interventions

	2011		2015		P
	Mean	(SE)	Mean	(SE)	
People not participating in the interventions					
Fasting blood glucose, mg/dL	98	(0.8)	105	(1.8)	<.001
2-hr glucose OGTT, mg/dL	144	(1.8)	121	(3.8)	<.001
People participating in the interventions					
Fasting blood glucose, mg/dL	102	(0.7)	102	(1.8)	.81
2-hr glucose OGTT, mg/dL	143	(1.9)	125	(3.2)	<.001

OGTT, oral glucose tolerance test; SE, standard error.

The promotoras used the Spanish-language Group Lifestyle Balance program participant hangout to deliver the sessions. The study highlights that LSI delivered by promotoras is superior to metformin and SC for weight reduction and provides evidence of a feasible way of implementation.

DPS-Based Strategies. The demonstration area for primary prevention of T2D, JUAN Mina and Barranquilla (DEMOJUAN) in Colombia, was the first attempt to implement the DPS⁹ in LA.⁶⁴ The main aim of the DEMOJUAN was to investigate to what extent it is possible to reach normal glucose metabolism with early lifestyle interventions in people at high risk of T2D compared with those who receive standard therapy (usual care). Study participants were recruited by opportunistic screening using the FINDRISC.^{21,46} People with 13 or more FINDRISC points (35%, n = 4915) were invited to an OGTT and those with IGT or IFG were invited to join the interventions. The DEMOJUAN study randomly assigned the participants into 3 groups: (i) lifestyle intervention starting with 6 months of nutritional intervention followed by 6 months of nutritional and physical activity interventions; (ii) lifestyle intervention starting with 6 months of physical activity intervention followed by 6 months of physical activity and nutritional interventions; and (iii) control group. In the second year, both intervention groups received physical activity and nutritional interventions. This study found that 2-hour glucose levels decreased in both the control and intervention group approximately 20 mg/dL during the 4 years of the project. This reduction is important considering that at the end of the study almost 50% of the people with abnormal glucose regulation reverted to normoglycemia (Table 4).

Thus, DEMOJUAN indicated that programs with early lifestyle intervention within primary health care

system targeting people with IFG, IGT, or both, may be beneficial. In the US DPP, the conversion rate to normal glucose over approximately 3 years was similar to DEMOJUAN (50%) in the lifestyle group and lower (20%) in the placebo group.⁸ Thus, the difference in DEMOJUAN compared with DPP was that the control group had a larger conversion rate to normoglycemia.

It was a surprise that the improvement in glucose profile was similar in both the intervention and control groups. Several reasons may explain these findings. First, probably just participating in this study encouraged the people in the control group to adopt a healthier lifestyle. Actually, the participants in the control group were told about their high risk of T2D, and they also received “mini-intervention” to improve their lifestyle (Hawthorne effect). Second, during the study many activities were carried out by the city of Barranquilla targeting people with glucose metabolism disorders. For instance, environmental changes were implemented in the city in the form of creation of parks and special sites where people can practice physical activity. In addition, there were steady information campaigns targeting people with overweight and obesity to adopt a healthier lifestyle to avoid T2D. The DEMOJUAN initiative was supported by the Ministry of Health of Colombia declaring Barranquilla as the national demonstration area for diabetes prevention.

The problem with translational research in implementing designs of randomized clinical controlled trials in a real-life setting is that some factors cannot be controlled. The political agenda to work on diabetes prevention affects the entire population. Thus, in order to control for this, a randomized clinical controlled trial in a laboratory setting, such as the DPS, IDPP, or DPP studies, should be designed.^{8,9,12} However, this was not the goal of this study.

CONCLUSIONS

Screening for high-risk individuals and implementing diabetes prevention programs require validation of risk scores in each setting and transculturalization of lifestyle recommendations, taking in account ethnic and cultural differences. The transculturalization process overcomes

many barriers to implementation. In LA some experiences in FINDRISC score validation and DPP- and DPS-based strategies have been developed. The future of transculturalization in diabetes prevention will be based on new data from clinical trials and practical experiences gained from other study designs performed in local settings with application of culturally adapted strategies.

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