Effective Translation of an Intensive Lifestyle Intervention for Hispanic Women With Prediabetes in a Community Health Center Setting

Michelle A. Van Name,[1] Anne W. Camp,[2] Elizabeth A. Magenheimer,[2] Fangyong Li,[3] James D. Dziura,[3] Abmaridel Montosa,[2] Anisha Patel,[1] and William V. Tamborlane[1]

Diabetes Care 2016;39:525–531 | DOI: 10.2337/dc15-1899

OBJECTIVE

The Diabetes Prevention Program (DPP) demonstrated that weight loss from intensive lifestyle intervention (ILI) in adults with prediabetes could decrease progression to type 2 diabetes. Inner-city, low-income Hispanic women are at high risk for developing type 2 diabetes; however, this type of intervention is not well established in this group. We hypothesized that a DPP intervention modified for a community health center (CHC) setting would decrease weight and improve metabolic measures in Hispanic women with prediabetes.

RESEARCH DESIGN AND METHODS

Women diagnosed with prediabetes on a screening oral glucose tolerance test were recruited from a CHC. Participants (90% of whom were Hispanic) were randomized to either usual care (age 43 ± 9.7 years, BMI 35.2 ± 7.3 kg/m^2) or ILI (age 43.8 ± 10.8 years, BMI 35.4 ± 8.5 kg/m^2), structured as 14 weeks of group sessions focused on food choices, behavior change, physical activity, and weight loss. One year after enrollment, 122 women repeated baseline measures.

RESULTS

Groups had similar baseline weight, BMI, and fasting and 2-h glucose. One year later, the ILI group had lost 3.8 kg (4.4%), while the usual care group had gained 1.4 kg (1.6%, $P < 0.0001$). Two-hour glucose excursion decreased 15 mg/dL (0.85 mmol/L) in the ILI and 1 mg/dL (0.07 mmol/L) in the usual care group ($P = 0.03$). Significant decreases favoring the ILI group were noted in BMI, percent body fat, waist circumference, and fasting insulin.

CONCLUSIONS

A 14-week ILI program based on the DPP can effectively be translated into a predominantly Hispanic CHC setting, resulting in decreased weight, improved fasting insulin, and smaller glucose excursions 1 year after enrolling in the program.

As the epidemic of type 2 diabetes continues unabated, major racial, ethnic, and economic disparities in its prevalence and complications persist in the U.S. Hispanics are particularly hard-hit, with almost twice the rate of diabetes (12.8%) as non-Hispanic whites (7.6%), and an additional 38% have prediabetes (1). One in two Hispanic females born in the year 2000 is predicted to develop type 2 diabetes in her

[1]*Division of Pediatric Endocrinology, Department of Pediatrics, Yale University School of Medicine, New Haven, CT*
[2]*Fair Haven Community Health Center, New Haven, CT*
[3]*Yale School of Public Health, Yale University, New Haven, CT*

Corresponding author: Anne W. Camp, a.camp@fhchc.org.

Received 31 August 2015 and accepted 14 January 2016.

This article contains Supplementary Data online at http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dc15-1899/-/DC1.

lifetime (2). Poverty also plays a role; in Connecticut, adults with annual household incomes below $25,000 are 2.6 times more likely to have diagnosed diabetes compared with adults with incomes over $75,000 (3). Widespread implementation of effective programs to prevent type 2 diabetes targeted toward these disadvantaged groups is a public health imperative.

The National Institute of Diabetes and Digestive and Kidney Diseases–supported Diabetes Prevention Program (DPP) (4) was a large-scale, randomized clinical trial, which demonstrated that weight loss and increased physical activity through an intensive lifestyle intervention (ILI) in individuals with prediabetes can delay or prevent the progression to type 2 diabetes. Compared with the results in conventionally treated control subjects, new cases of type 2 diabetes were reduced by 58% in subjects randomized to the ILI. While this trial achieved racial and ethnic diversity, only 15.7% of participants were Hispanic, and a minority were of lower educational or socioeconomic status (5).

In the 13 years since its publication, the findings of the landmark DPP trial have not been widely translated into practice, particularly in disadvantaged populations and settings. There are multiple obstacles to making such interventions available in these settings, including limited access to safe areas to exercise in poor inner-city neighborhoods and lack of Spanish-speaking staff. Community organizations often do not have the financial resources to cover the staff time and effort required to carry out ILI programs. Another important impediment to translation of the DPP results into better health for disadvantaged populations is the limited evidence from community-based studies that diabetes prevention programs can be effective in settings where most patients are from low-income ethnic and racial minority groups. Prior studies adapting DPP interventions to community-based interventions in Hispanic populations have shown modest improvements in body weight from lifestyle intervention programs (6,7).

Uniquely situated to address this need are Community Health Centers (CHCs), which constitute the largest primary care system for underserved populations in the U.S. CHCs serve over 21 million patients across all 50 states (8). They play a crucial role in providing primary and preventive care to racial and ethnic minorities and low-income groups at high risk for type 2 diabetes. As such, CHCs can serve as an important access point for community-based prevention programs.

The Fair Haven Community Health Center (FHCHC), a federally qualified CHC in New Haven, CT, provides an example of the looming crisis in diabetes care that many such health centers face today. FHCHC primarily serves an inner-city Hispanic population, in which 68% of women over age 18 years are obese, 38% have prediabetes, and 20% have type 2 diabetes, far exceeding national rates. In response to these demographics, the leadership of FHCHC committed the resources to create a comprehensive prevention program including a diabetes screening program and DPP-based group ILI program with the stipulation that continuing support for the program depended on the demonstration of its effectiveness in terms of reductions in body weight and improvements in glucose tolerance. In order to gather this evidence, clinicians at FHCHC collaborated with investigators in Yale's Clinical and Translational Science Award Community Engagement Group to develop and implement a randomized clinical trial of the FHCHC ILI. The results of the study are reported herein.

RESEARCH DESIGN AND METHODS

Study Participants

The FHCHC is medical home to >15,000 residents of an urban community in which 72% of adults are Hispanic, 18% African American, 9% non-Hispanic white, and 1% other; >60% are best served in a language other than English. The FHCHC population is poor: 90% of families have an annual income <100% of the federal poverty level and 99% of families fall below 200% of the federal poverty level (9). At the time of the study, health insurance coverage status was typical of other CHCs: 51% Medicaid, 7% Medicare, 10% commercial, and 32% uninsured.

The center's electronic patient registry (Patient Electronic Care System [PECSYS]) was used from 2008 to 2012 to identify women between 18 and 65 years of age with at least one risk factor for diabetes, including BMI $\geq$30 kg/m^2, a family history of type 2 diabetes, a history of gestational diabetes mellitus, a child born >9 pounds (4 kg), or a diagnosis of hypertension, dyslipidemia, or cardiovascular disease. On the basis of these criteria, 1,093 women identified as being at risk were screened at the health center with an oral glucose tolerance test (OGTT). As per American Diabetes Association criteria (10), a patient was classified as having prediabetes if fasting plasma glucose was 100 mg/dL (5.6 mmol/L) to 125 mg/dL (6.9 mmol/L) or if 2-h plasma glucose (2-h plasma glucose [PG]) was 140 mg/dL (7.8 mmol/L) to 199 mg/dL (11 mmol/L). Hemoglobin A_{1c} (HbA_{1c}) was measured; however, it was not used as inclusion criteria in this study. Three hundred eighty-three women aged 18–65 years were found to have prediabetes, of whom 42 were ineligible based on the inclusion and exclusion criteria. Subjects were excluded from the study if they were pregnant or planning to become pregnant, were taking medications that would affect weight or glucose metabolism, or had chronic medical or psychiatric disorders that would interfere with their ability to participate in the exercise or other components of the ILI program. We were able to reach 262 eligible participants via phone to offer enrollment in the study, which was reviewed and approved by the Yale Human Investigation Committee and the institutional review board of FHCHC. Written informed consent was obtained by bilingual study staff from all subjects who agreed to participate using consent forms written in either Spanish or English.

Study Design

The study was designed as a parallel-group, randomized control trial, in which eligible subjects were randomized in a 1:1 ratio to either the usual care group or the ILI group. The primary outcome of the study was the difference between the two groups in change in body weight from baseline to the end of the 12-month study. The most important secondary end point was the response to OGTT. Other important secondary outcomes were changes in fasting plasma insulin, HbA_{1c}, lipids, and alanine aminotransferase (ALT) levels as well as HOMA of insulin resistance (HOMA-IR), blood pressure, waist circumference, and body composition.

Treatment Groups

Usual Care Group

Subjects randomized to the usual care group continued to receive follow-up care by their primary care provider at the FHCHC. In addition, they received one-time diabetes prevention counseling by study staff who recommended they lose 7% of their body weight and increase physical activity to 150 min/week. Follow-up dietary counseling by the center's nutritionist was offered. This is the standard care provided to patients diagnosed with prediabetes in this CHC. At the end of 12 months upon study conclusion, these subjects were offered entry into the ILI program.

ILI

The FHCHC ILI is a modified version of the National Institute of Diabetes and Digestive and Kidney Diseases DPP intervention. It consists of a family-centered 14-week group program held in the classrooms and cafeteria of a public school near the health center. Participants attend a 1-h lifestyle class one evening per week, which focuses on healthy food choices, behavior change, and weight loss. The curriculum closely follows the sequence and materials from the DPP Research Group (11). The curriculum was enhanced for a population with lower literacy with a hands-on learning approach including weekly cooking demonstrations using fresh ingredients harvested from FHCHC's community garden, group learning sessions at the local grocery store, and encouragement to participate in the neighborhood community farm. The weekly program is led and supervised by a bilingual nurse practitioner from the CHC, who received training in the DPP curriculum at the University of Pittsburgh's Diabetes Prevention Support Center. Classes are conducted in both English and Spanish, and all handouts and presentation materials are also bilingual. A 1-h, trainer-led group exercise class occurs 2–3 nights per week, with 1 night per week offered immediately after the lifestyle class. For facilitation of class attendance and a family-based approach at home, participants are encouraged to attend with family members, including children and babies. A parallel program of play-based physical activity for children and adolescents and child care for the youngest are offered simultaneously at the school.

Procedures

At enrollment, anthropometric measures were obtained including height (stadiometer), weight, and body composition by body fat analyzer (TBF-300; Tanita, Arlington Heights, IL), waist circumference, and blood pressure; BMI was calculated.

An OGTT was performed at baseline and at the end of the 12-month study. On both occasions, subjects were studied at ~8:00 A.M. after a 10- to 12-h overnight fast. Baseline blood samples were obtained for measurement of HbA_{1c} and fasting plasma lipids, insulin, and glucose levels. Subjects then ingested 75 g oral glucose (Glucola), and a second plasma sample was obtained 2 h later to measure plasma glucose levels. The 2-h glucose excursion was defined as the difference between the baseline and 2-h PG level. HOMA-IR was calculated using the OGTT according to the equation HOMA-IR = fasting insulin in μU/mL $\times$ fasting glucose in mmol/L divided by 22.5 (12).

Analytical Methods

Glucose, lipids, HbA_{1c}, aspartate aminotransferase, and ALT were measured by Quest Diagnostics (Wallingford, CT), whose quality-assurance methods meet standards mandated by Clinical Laboratory Improvement Amendments. Fasting plasma insulin levels were measured using a double-antibody radioimmunoassay (EMD Millipore, Billerica, MA).

Statistical Analysis

The sample size estimation was based on the following assumptions: *1*) two-sided 0.05 significance level and 90% power, *2*) a minimum detectable 1-year treatment difference of 4 kg, and *3*) a conservative estimate of the SD for 1-year weight change of 7.1 kg, based on 1-year weight change observed in the DPP (4). Thus, the goal sample size was 68 subjects per group, with a plan to randomize 75 subjects per group to account for a 10% drop-out rate.

Baseline data and 1-year changes from baseline are represented as mean and SD, analyzed using independent and paired *t* tests, respectively, and conducted using GraphPad Prism, version 6.0 (La Jolla, CA). Linear contrasts were used to obtain changes at 1 year from baseline and compare the changes between randomized groups. Mixed-model repeated-measures analysis was conducted to include all available observations and control for baseline measures. Because 36 subjects did not have insulin measures at both baseline and follow-up, logistic regression examined whether baseline characteristics and outcome measures were associated with missingness. The percent missingness was not significantly different between the ILI (n = 20) and usual care (n = 16) groups (χ^2 P = 0.43). BMI and body fat were significant predictors and thus were included in the model for covariate adjustment. Least squares means and 95% CIs for each group and the difference between groups (intervention effect) are presented. The significance level was set at $P < 0.05$, two-sided, and analysis carried out using SAS 9.3 (SAS Institute, Cary, NC).

RESULTS

Baseline Characteristics

One hundred thirty women were enrolled in the study. Ninety percent were Hispanic, 8% were African American, and 2% were non-Hispanic Caucasian. Sixty-five subjects were randomized to each group. In the ILI group, three subjects were removed from the study when they became pregnant and one subject was lost to follow-up, and in the usual care group, four subjects voluntarily withdrew from the study. Thus, 61 subjects in each group were included in the final analysis. As shown in Table 1, the two groups were similar in terms of age, weight, BMI, and body fat at baseline. Metabolic measurements revealed similar fasting and 2-h PG as well as HbA_{1c} levels. Despite similar glycemia, fasting insulin differed by group and thus HOMA varied as well. Total cholesterol, LDL, and triglycerides also differed between the groups, while HDL was similar at baseline.

Changes in Adiposity and Metabolism

All 61 subjects in each group had a follow-up weight and BMI obtained at 1 year. As shown in Table 2 and Fig. 1, there were significant differences between the ILI and usual care groups regarding change in weight, percent weight, body fat, and waist circumference, which were all strikingly improved in the ILI group but worsened or varied little from baseline in the usual care group. The ILI group lost 3.19 kg (3.58%) in body weight at the end of the 14-week program and

Table 1—Main anthropometric and biochemical values at baseline

	ILI (*N* = 61)	Usual care (*N* = 61)	*P*
Age, years	43.8 ± 10.8	43.0 ± 9.7	0.684
Weight, kg	84.8 ± 24.8	87.1 ± 22.8	0.586
BMI, kg/m^2	35.4 ± 8.5	35.2 ± 7.3	0.916
Body fat, %	42.2 ± 7.1	43.5 ± 6.1	0.296
Waist circumference, cm	106.9 ± 15.4	109.0 ± 15.0	0.449
Systolic blood pressure, mmHg	119.1 ± 19.0	123.0 ± 16.7	0.225
Diastolic blood pressure, mmHg	77.3 ± 11.3	79.8 ± 11.0	0.213
Metabolic profile			
Fasting glucose, mg/dL (mmol/L)	102 ± 9.5 (5.7 ± 0.5)	101.5 ± 11.1 (5.6 ± 0.6)	0.807
2-h glucose, mg/dL (mmol/L)	146.7 ± 29.4 (8.1 ± 1.6)	143.2 ± 29.8 (7.9 ± 1.7)	0.518
2-h glucose excursion, mg/dL (mmol/L)	44.7 ± 32.2 (2.5 ± 1.8)	41.7 ± 34.8 (2.3 ± 1.9)	0.620
Fasting insulin, μU/mL (pmol/L)	23.6 ± 12.0 (141.6 ± 72)	34.0 ± 14.2 (204 ± 85.2)	0.0004
HOMA-IR	6.0 ± 3.3	8.5 ± 4.0	0.0019
HbA_{1c}, % (mmol/mol)	5.8 ± 0.36 (40 ± 3.9)	6.0 ± 0.33 (42 ± 3.6)	0.072
ALT, units/L	27 ± 18.8	26.5 ± 26.6	0.915
Lipids			
Total cholesterol, mg/dL (mmol/L)	199.5 ± 39.6 (5.2 ± 1.0)	181.4 ± 31.2 (4.7 ± 0.8)	0.006
LDL cholesterol, mg/dL (mmol/L)	118 ± 35.4 (3.1 ± 0.9)	106.2 ± 25.8 (2.7 ± 0.7)	0.038
HDL cholesterol, mg/dL (mmol/L)	49.5 ± 12.7 (1.3 ± 0.3)	49.0 ± 9.7 (1.3 ± 0.3)	0.83
Triglycerides, mg/dL (mmol/L)	162.7 ± 87.2 (1.8 ± 0.9)	129.1 ± 52.3 (1.4 ± 0.6)	0.012

Data are means ± SD. *P* value represents result of an independent *t* test.

had a total of 3.8 kg weight loss (−4.4%) at the end of 12 months, whereas the usual care group gained 1.4 kg (1.6%) at 12 months.

While fasting glucose remained fairly stable in both groups, the mean glucose excursion was significantly diminished in the ILI compared with usual care group. The decrease in fasting insulin was significantly larger in the ILI compared with the usual care group. Although there was a significant improvement in HOMA-IR within the ILI group but not within the usual care group (Supplementary Table 1), the changes in insulin sensitivity between the two groups did not meet the significance threshold. Statistically significant improvements were noted in HDL and triglycerides in the ILI group compared with usual care group.

While the study was not powered to detect differences in rates of normalization or deterioration of blood glucose control, at the 1-year follow up, three subjects in the ILI group and four in the usual care group had progressed from prediabetes to diabetes. Twelve subjects in the ILI group and 10 in the usual care group reverted to normal glucose tolerance.

Attendance of the ILI sessions varied, with 4 subjects (7%) attending 0–2 classes and 42 subjects (68%) attending at least 14 classes. Percent weight loss positively correlated with this amount of exercise and lifestyle class (Fig. 2).

Data comparing within-group changes from baseline in these anthropometric and metabolic parameters are shown in Supplementary Table 1.

CONCLUSIONS

This study demonstrates the feasibility and effectiveness of an ILI program in a CHC setting caring for predominantly low-income Hispanic patients. The ILI was enthusiastically received by most of the subjects and achieved clinically and statistically significant changes in body weight and BMI over 12 months in these patients with prediabetes. The 5.2-kg (6%) difference in body weight between the two groups at 12 months was greater than we anticipated and, if sustained, would be expected to delay or reduce the risk of developing type 2 diabetes (4).

The substantial improvement in glucose tolerance in the ILI group, as reflected by the 18.9 mg/dL (1.05 mmol/L) lowering of 2-h PG excursion and 2-h PG during the OGTT, was an important secondary outcome of the study, since elevations in the 2-h PG in the prediabetes range have been identified as a biomarker of risk for future cardiovascular disease and other negative health outcomes (13,14). Although fasting glucose levels were not statistically different between the two groups at 1 year, the larger decrease in fasting plasma insulin concentrations in the ILI group may reflect an improvement in insulin sensitivity resulting from the ILI dietary and exercise changes. The failure to achieve statistically significant changes in insulin sensitivity between the two groups is likely to be due to the marked discrepancies in baseline fasting plasma insulin levels at the start of the study, as well as the number of missing plasma insulin samples at the end of the study.

Additionally, the significant improvements observed in waist circumference, triglycerides, and HDL in the ILI group compared with control are of clinical importance, as the metabolic syndrome has also been linked to risk of cardiovascular outcomes (15). Despite higher fasting insulin, the total cholesterol, LDL, and triglycerides were lower in the usual care group at baseline. Triglycerides significantly decreased in the ILI compared with usual care at 1 year. While they did not reach statistical significance, improvements were also noted in the ILI group's total cholesterol, LDL, and HDL, as might be expected given the decrement in weight, BMI, waist circumference, glucose, and insulin.

The ILI program's reputation in the community and its family- and community-based approach (e.g., holding the sessions

Table 2—Change in anthropometric and metabolic measures from baseline to 1 year

	ILI	Usual care	Effect	*P*
Weight, kg	−3.8 (−4.6 to −3.0)	1.4 (0.6 to 2.2)	−5.2 (−6.4 to −4)	<0.0001
Weight, %	−4.4 (−5.4 to −3.5)	1.6 (0.7 to 2.6)	−6 (−7.4 to −4.7)	<0.0001
BMI, kg/m^2	−1.6 (−2 to −1.3)	0.6 (0.2 to 0.9)	−2.2 (−2.7 to −1.7)	<0.0001
Body fat, %	−1.9 (−2.9 to −1.0)	0.4 (−0.7 to 1.4)	−2.3 (−3.8 to −0.9)	0.002
Waist circumference, cm	−3.3 (−5.2 to −1.4)	−0.2 (−2.1 to 1.7)	−3.1 (−5.8 to −0.5)	0.02
Systolic blood pressure, mmHg	−1.5 (−5.0 to 2.1)	0 (−3.6 to 3.6)	−1.4 (−6.0 to 3.1)	0.53
Diastolic blood pressure, mmHg	−0.5 (−2.8 to 1.7)	−0.9 (−3.2 to 1.4)	0.4 (−2.6 to 3.3)	0.80
Metabolic profile				
Fasting glucose, mg/dL (mmol/L)	−3.5 (−6.2 to −0.8) (−0.19 [−0.34 to −0.04])	−4.5 (−7.2 to −1.8) (−0.25 [−0.39 to −0.1])	0.9 (−2.7 to 4.6) (0.05 [−0.15 to 0.26])	0.61
2-h glucose, mg/dL (mmol/L)	−18.9 (−29 to −8.8) (−1.05 [−1.61 to −0.49])	−5.5 (−15.7 to 4.7) (−0.31 [−0.87 to 0.26])	−13.4 (−27.1 to 0.3) (−0.74 [−1.5 to 0.02])	0.055
2-h glucose excursion, mg/dL (mmol/L)	−15.3 (−25.1 to −5.6) (−0.85 [−1.39 to −0.31])	−1 (−10.8 to 8.8) (−0.0 [−0.6 to 0.49])	−14.4 (−27.2 to −1.5) (−0.8 [−1.5 to −0.08])	0.03
Fasting insulin, μU/mL (pmol/L)‡*	−3.1 (−4.8 to −1.2) (−18.6 [−28.8 to −7.2])	0.3 (−2.2 to 1.8) (1.8 [−13.2 to 10.8])	−2.8 (−4.9 to −0.2) (−16.8 [−29.4 to −1.2])	0.03
HOMA-IR‡*	−1 (−1.4 to −0.5)	0.3 (−0.8 to 0.3)	−0.7 (−1.3 to −0.0)	0.06
HbA_{1c}, % (mmol/mol)	−0.1 (−0.1 to 0.0) (−1.1 [−1.1 to 0.0])	0.0 (−0.1 to 0.1) (0.0 [−1.1 to 1.1])	0.0 (−0.1 to 0.1) (0.0 [−1.1 to 1.1])	0.30
ALT, units/L	−5.2 (−9.7 to −0.7)	−3.9 (−8.5 to −0.7)	−1.3 (−6.0 to 3.4)	0.59
Lipids				
Total cholesterol, mg/dL (mmol/L)	−6.3 (−12.4 to −0.1) (−0.16 [−0.31 to −0.0])	−2.4 (−8.6 to 3.8) (−0.06 [−0.22 to 0.1])	−3.9 (−12.3 to 4.5) (−0.1 [−0.31 to 0.12])	0.36
LDL cholesterol, mg/dL (mmol/L)	−3.7 (−9.5 to 2) (−0.09 [−0.24 to 0.05])	−4.5 (−10.3 to 1.4) (−0.11 [−0.26 to 0.04])	0.8 (−6.9 to 8.4) (0.02 [−0.18 to 0.22])	0.84
HDL cholesterol, mg/dL (mmol/L)	1.8 (−0.2 to 3.8) (0.05 [−0.01 to 0.1])	−1.0 (−3 to 1.0) (−0.03 [−0.08 to 0.03])	2.8 (−0.0 to 5.5) (0.07 [−0.0 to 0.14])	0.049
Triglycerides, mg/dL (mmol/L)	−20 (−49 to 8.9) (−0.22 [−0.55 to 0.1])	29.4 (0.1 to 58.7) (0.33 [0.0 to 0.66])	−49.4 (−90.6 to −8.3) (−0.55 [−1.01 to −0.09])	0.02

Data are represented as least squares mean (after adjustment for baseline) and CI. *P* value represents the results of mixed-model repeated-measures analysis that included all available data and controlled for baseline values. ‡Data are presented using geometric means. *Analysis was adjusted for baseline BMI and body fat, which are associated with missingness at baseline (36 patients did not have insulin values).

in a local school, providing activities for children during the sessions, and linking dietary counseling sessions to urban farming activities [16]) likely contributed to the success of this intervention. Health center activities to promote clinician knowledge and buy-in for this ongoing ILI program strengthened referrals for screening and may also have contributed to participation and ultimate study success. Additional measures to increase attendance may further improve outcomes given the significant correlation of class attendance and percent weight loss.

Like other CHCs, FHCHC exists at the nexus of the community and the health care system and therefore can create important connections for lifestyle changes and self-management support. Because their trained medical staff already provides a broad range of services, CHCs may be able to implement labor-intensive programs that would be impossible to carry out in smaller internal medicine practices. Nevertheless, it remains to be established whether and to what extent programs such as ours can be disseminated to other CHCs.

While the number of Hispanics are projected to more than double by 2060, constituting 28.5% of the U.S. population (17), only two previous randomized controlled trials have examined the efficacy of adapting DPP methods for use in a predominantly low-income Hispanic population. Though the changes in body weight and other anthropometric measures in those studies were similar to those seen in our subjects, neither study used the OGTT to evaluate metabolic benefits of the ILI, and in both studies, the relative reductions in body weight were modest. For example, in a large clinical trial completed by 289 obese or overweight Latino adults, the difference in body weight in subjects randomized to the ILI versus control subjects was only 2.5 lbs (1.1 kg) upon conclusion of the 1-year intervention (6). In a much smaller study, body weight in the 38 overweight or obese Mexican Americans randomized to the ILI group was 2.8 kg lower than in the 20 control subjects after completion of the 5-month study (7). The durable success of the 14-week intervention used in our study was shown by the 5.2-kg difference in body weight versus control subjects 8–9 months after completion of the ILI and by a mean 5.09% weight loss at 12 months in subjects attending at least four sessions, meeting the CDC standard of 5% weight loss in DPP programs (18). Our findings, in combination with the results from previous studies, serve to highlight the benefits of implementing DPP-style interventions to high-risk minority populations in community settings. While prior studies also focused on a culturally appropriate community-delivered intervention, the larger weight loss achieved in this study may be due to the higher frequency of sessions during the short intervention,

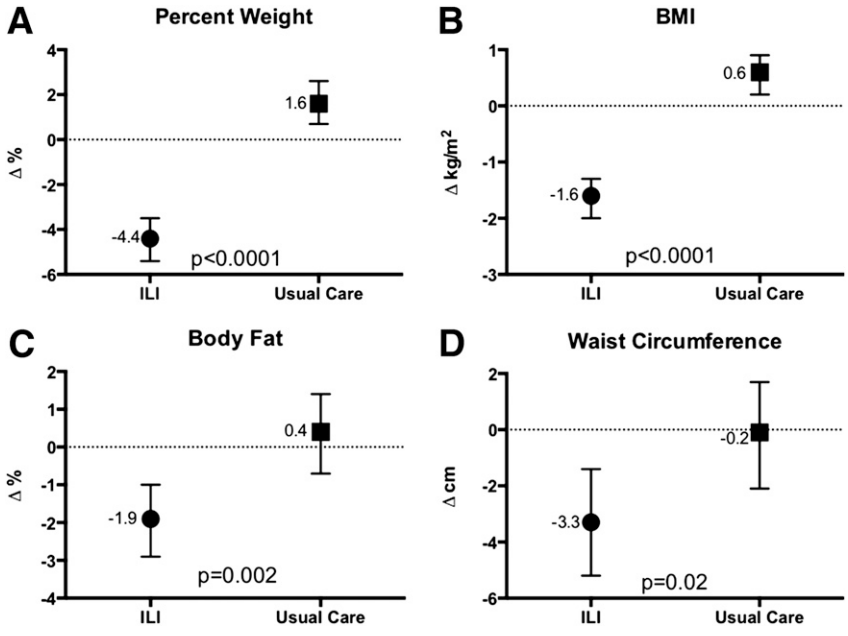

Figure 1—Change from baseline to 1 year. Plotted points represent the least squares mean and error bars reflect the 95% CI for change in percent weight (*A*), BMI (*B*), body fat (*C*), and waist circumference (*D*). *P* values represent the results of mixed-model repeated-measures analysis that included all available data and controlled for baseline values.

group exercise, and availability of children's activity and child care to eliminate that barrier to attendance. Continued improvements are needed to reach the 7.1% weight loss achieved by Hispanic women in the original DPP study (19).

This trial, designed as a pragmatic translational pilot study, had a number of limitations. Because of the added costs, we did not carry out more comprehensive metabolic assessments, such as more frequent insulin measurements during the OGTT or DEXA scans to assess changes in body composition. We were able to enroll 65 subjects per group, and 61 subjects per group completed the study, which was just short of our goal sample size. Despite the randomization procedures that produced two groups of similar age and BMI at baseline, there were significant differences in baseline fasting plasma lipid and insulin concentrations, which are difficult to explain. Since 90% of the study participants were Hispanic women, the findings of the study may not be generalizable to programs with mixed sexes and other racial or ethnic groups. On the other hand, we have recently shown that an ILI program like that used in this study (Yale Bright Bodies Program) is also effective in reversing prediabetes in ethnically diverse, obese, inner-city adolescents (20).

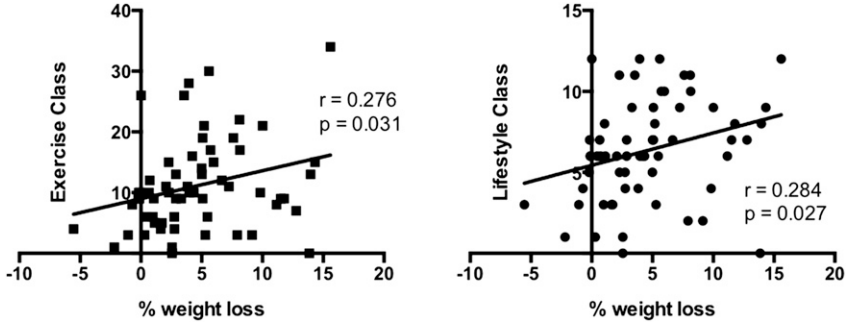

Figure 2—Relationship of weight loss and attendance. Plotted points represent number of classes attended and percent weight loss in each subject in the ILI group. Pearson correlation was used for statistical analysis.

While subjects in the ILI group had lowered their body weight and 2-h PG glucose levels to a greater extent than in the usual care group, only 20% of the ILI group had normalized 2-h PG levels and 5% went on to develop type 2 diabetes. On the basis of these results, there remains room for improvement in clinical outcomes. For further reduction of type 2 diabetes in high-risk populations, a combined approach using an ILI program like the one used in this study, community-based educational programs (16) aimed at preventing obesity, and pharmacologic agents that promote weight loss and reverse early β-cell dysfunction should be evaluated. This strategy can additionally focus on body composition, fitness, and other variables associated with improved cardiovascular outcomes to decrease rates of type 2 diabetes and its complications in high-risk communities in the future.

Acknowledgments. The authors thank the staff of the Yale Center for Clinical Investigation Core Laboratory for conducting the insulin assays.
Funding. This work was supported by the Donaghue Program for Research Leadership (DF08-313) and Fair Haven Community Health Center, as well as National Institutes of Health grants UL1-TR-000142, P30-DK-045735, and K12-DK-094714.
Duality of Interest. W.V.T. is a consultant for Medtronic, Novo Nordisk, Sanofi, AstraZeneca, Takeda, and Unomedical. No other potential conflicts of interest relevant to this article were reported.
Author Contributions. M.A.V.N., F.L., and J.D.D. conducted data analysis. A.W.C., E.A.M., and W.V.T. were responsible for the study conduct and data collection. A.W.C., E.A.M., and A.M. were responsible for the data collection. M.A.V.N., A.W.C., E.A.M., and W.V.T. contributed to the interpretation of data. M.A.V.N., A.W.C., A.P., and W.V.T. wrote and edited the manuscript. A.W.C. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Prior Presentation. Parts of this study were presented in abstract form at the 73rd Scientific Sessions of the American Diabetes Association, Chicago, IL, 21–25 June 2013.

References

1. Centers for Disease Control and Prevention. *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014*. Atlanta, GA, U.S. Department of Health and Human Services, 2014

2. Narayan KM, Boyle JP, Thompson TJ, Sorensen SW, Williamson DF. Lifetime risk for diabetes mellitus in the United States. JAMA 2003;290:1884–1890

3. Connecticut Department of Public Health. *The Burden of Diabetes in Connecticut 2010 Surveillance Report*. Hartford, CT, Connecticut Department of Public Health, 2011
4. Knowler WC, Barrett-Connor E, Fowler SE, et al.; Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002;346:393–403
5. The Diabetes Prevention Program Research Group. The Diabetes Prevention Program: baseline characteristics of the randomized cohort. Diabetes Care 2000;23:1619–1629
6. Ockene IS, Tellez TL, Rosal MC, et al. Outcomes of a Latino community-based intervention for the prevention of diabetes: the Lawrence Latino Diabetes Prevention Project. Am J Public Health 2012;102:336–342
7. Vincent D, McEwen MM, Hepworth JT, Stump CS. The effects of a community-based, culturally tailored diabetes prevention intervention for high-risk adults of Mexican descent. Diabetes Educ 2014;40:202–213
8. U.S. Department of Health and Human Services. 2014 health center data: health center program grantee data [Internet]. Available from http://bphc.hrsa.gov/uds/datacenter.aspx. Accessed 4 August 2015
9. Computations for the 2013 Annual Update of the HHS Poverty Guidelines for the 48 Continugous States and the District of Columbia [Internet]. Washington, DC, U.S. Department of Health and Human Services. Available from http://aspe.hhs.gov/poverty/13computations.cfm. Accessed 28 November 2014
10. American Diabetes Association. Classification and diagnosis of diabetes. Sec. 2. In *Standards of Medical Care in Diabetes—2015*. Diabetes Care 2015;38(Suppl.):S8–S16
11. Diabetes Prevention Program (DPP) Research Group. The Diabetes Prevention Program (DPP): description of lifestyle intervention. Diabetes Care 2002;25:2165–2171
12. Yeckel CW, Weiss R, Dziura J, et al. Validation of insulin sensitivity indices from oral glucose tolerance test parameters in obese children and adolescents. J Clin Endocrinol Metab 2004;89:1096–1101
13. Qiao Q, Pyörälä K, Pyörälä M, et al. Two-hour glucose is a better risk predictor for incident coronary heart disease and cardiovascular mortality than fasting glucose. Eur Heart J 2002;23:1267–1275
14. Blake DR, Meigs JB, Muller DC, Najjar SS, Andres R, Nathan DM. Impaired glucose tolerance, but not impaired fasting glucose, is associated with increased levels of coronary heart disease risk factors: results from the Baltimore Longitudinal Study on Aging. Diabetes 2004;53:2095–2100
15. Gami AS, Witt BJ, Howard DE, et al. Metabolic syndrome and risk of incident cardiovascular events and death: a systematic review and meta-analysis of longitudinal studies. J Am Coll Cardiol 2007;49:403–414
16. Hanc J. What the doctor ordered: urban farming. *New York Times*, 7 Nov 2014: Special Section: Giving, p. F4
17. Colby S, Ortman J. *Projections of the Size and Composition of the U.S. Population: 2014 to 2060 Population Estimates and Projections*. Washington, DC, United States Census Bureau, 2014
18. Centers for Disease Control and Prevention. *Centers for Disease Control and Prevention Diabetes Prevention Recognition Program Standards and Operating Procedures*. Atlanta, GA, Centers for Disease Control and Prevention, January 2015
19. West DS, Elaine Prewitt T, Bursac Z, Felix HC. Weight loss of black, white, and Hispanic men and women in the Diabetes Prevention Program. Obesity (Silver Spring) 2008;16:1413–1420
20. Savoye M, Caprio S, Dziura J, et al. Reversal of early abnormalities in glucose metabolism in obese youth: results of an intensive lifestyle randomized controlled trial. Diabetes Care 2014;37:317–324