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*The Diabetes Educator* 2011 37: 680  
DOI: 10.1177/0145721711416257

The online version of this article can be found at:  
<http://tde.sagepub.com/content/37/5/680>

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# Comprehensive Diabetes Management Program for Poorly Controlled Hispanic Type 2 Patients at a Community Health Center

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*Acknowledgments:* We thank Paula Santiago-Kelley, RN, Zoraida Rodriguez, RD, and Jane Garb, MS, for their contributions to this study.

Funding Source: This study was funded by Baystate Medical Center Academic Affairs Internal Research Grant #AA-BMC P99.

DOI: 10.1177/0145721711416257

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Technology and improved care coordination models can help diabetes educators and providers meet national care standards and provide culturally sensitive diabetes education that may improve diabetes outcomes. The purpose of the study was to evaluate the clinical usefulness of a nurse-led diabetes care program (Comprehensive Diabetes Management Program, CDMP) for poorly controlled Hispanic type 2 diabetes (T2DM) patients in an urban community health center setting. Patients were randomized to the intervention condition (IC; n = 21) or an attention control condition (AC; n = 18). IC and AC conditions were compared on rates of adherence to national clinical practice guidelines (blood glucose, blood pressure, foot exam, eye exam), and levels of diabetes distress, depression, and treatment satisfaction. IC patients had a significant improvement in A1C from baseline to 12-month follow-up compared with AC ( $-1.6\% \pm 1.4\%$  versus  $-0.6\% \pm 1.1\%$ ;  $P = .01$ ). The proportion of IC patients meeting clinical goals at follow-up tended to be higher than AC for A1c (IC = 45%; AC = 28%), systolic blood pressure (IC = 55%; AC = 28%), eye screening (IC = 91%; AC = 78%), and foot screening, (IC = 86%; AC = 72%). Diabetes distress and treatment satisfaction also showed greater improvement for IC than AC ( $P = .05$  and  $P = .06$ , respectively), with no differences for depression. The CDMP intervention was more effective than an attention control condition in helping patients meet evidence-based guidelines for diabetes care.



The majority of diabetes morbidity and mortality is due to serious microvascular and macrovascular complications arising from persistently high blood glucose, blood pressure, and blood lipid levels. These complications include cardiovascular disease, blindness, kidney failure, amputations, and nerve damage.<sup>1</sup> Diabetes is associated with high human costs in terms of treatment burden and its negative impact on daily functioning and quality of life.<sup>2</sup> The direct and indirect costs of diabetes have now risen to \$218 billion.<sup>3</sup> Hispanic Americans with type 2 diabetes (T2DM) have poorer access to healthcare, a higher prevalence of diabetes (11.1% versus 6.4% compared with non-Hispanic whites), and a higher incidence of diabetes-related complications.<sup>4-6</sup>

Landmark diabetes trials have shown the benefit of tighter control of blood glucose, blood pressure, and blood lipids, and the need for annual eye, foot, and kidney exams in reducing microvascular and macrovascular complications.<sup>7</sup> However, a considerable gap exists between national evidence-based recommendations for diabetes and current clinical practice.<sup>8</sup> This reflects not only the current unfavorable regulatory and financial environment for preventative diabetes care,<sup>9</sup> but also a lack of clinical systems and practice tools to support clinician decision-making, teamwork, communication, and collaboration.

While an appropriate evidence-based medical treatment plan can significantly reduce diabetes complications, patient diabetes education and daily self-care behaviors carried out by the patient are of central importance in attaining good metabolic control and diabetes outcomes.<sup>10-12</sup> Many environmental and patient-level factors can influence patients' decision-making around self-management behaviors, such as insurance and economic barriers to healthcare access, role demands in work and family life, patient health beliefs and competing life priorities, psychiatric disorders, alcohol and drug abuse, low social support, low health literacy and visual problems, learning preferences, and cultural and social traditions and norms.<sup>13-17</sup> Typically, little time is spent in busy clinical settings capturing salient factors that influence a patient's decisions about treatment adherence (based on the unique constellation of an individual patient's barriers) and incorporating these into an integrated treatment approach.

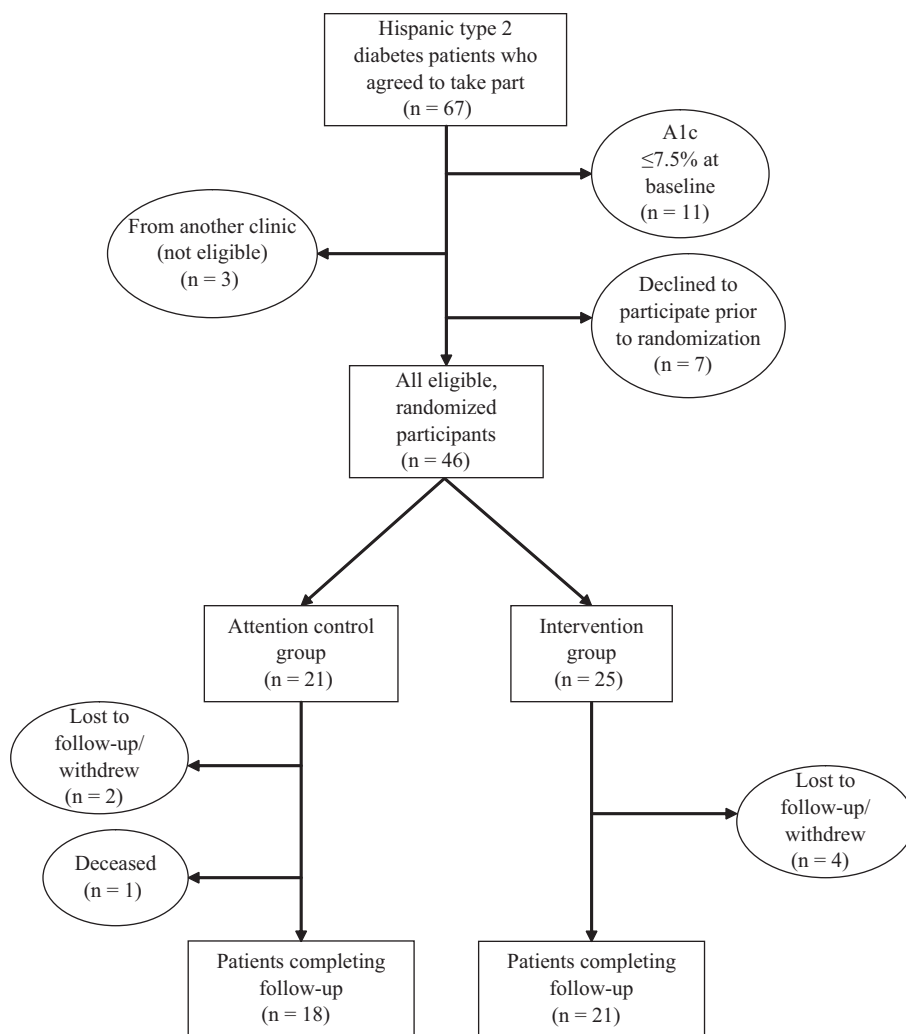
The Comprehensive Diabetes Management Program (CDMP)<sup>18</sup> is an interactive, Web-based, diabetes management tool based on American Diabetes Association (ADA) practice guidelines.<sup>19</sup> It was developed by a clinical research

consortium involving the Department of Defense, Veterans Affairs, the Indian Health Service, the Joslin Diabetes Center, and Baystate Medical Center in Springfield, Massachusetts. CDMP focuses on clinical management, lifestyle modification, and psychosocial health, and provides chronic care managers with a set of clinical and behavioral alerts that guide treatment decisions and structure the medical care and diabetes education plan. This program facilitates the aggregation and display of clinical data from a variety of sources, including clinical, laboratory, pharmacy, providers, and patients, and incorporates individual clinical alerts and composite treatment algorithms for cardiovascular disease, renal disease, peripheral vascular disease, blood glucose control, and retinopathy.<sup>20</sup> These data are augmented by a patient self-management assessment tool, the Diabetes Self-Care Profile (DSCP), which is completed by patients online and creates a set of diabetes behavioral alerts to guide self-management education and behavior change.<sup>21</sup> The DSCP assessment generates a 1-page summary report identifying barriers to self-care and psychosocial and attitudinal problems commonly seen in individuals with T2DM that can undermine the treatment plan.

In this study, the clinical usefulness of a comprehensive, diabetes care model for a Hispanic T2DM population seen at an urban community health center was assessed. Rates of diabetes control and key medical screening activities as well as patient psychosocial adjustment following the intervention were examined.

## Methods

A randomized controlled trial in adult Hispanic patients was conducted with poorly controlled T2DM to evaluate the clinical usefulness of the CDMP care model based on its impact on key diabetes outcomes and psychosocial adjustment. Participants were recruited from an urban community healthcare center (CHC) in Springfield, Massachusetts. The CHC serves a community with a high proportion of working poor, Medicaid eligible patients, and individuals with medical disabilities. Inclusion criteria were as follows: (i) duration of T2DM of at least 1 year based on medical record review and treatment history, (ii) age 30–85 years, (iii) A1C >7.5% within the past 3 months but not >14%, (iv) Hispanic ethnicity, and (v) independently living and ambulatory (ie, able to exercise by walking and attend study-related visits). Patients were excluded if they had severe diabetes complications, severe psychiatric illness,



**Figure 1.** Final study sample size.

or severe visual restrictions, or would not be available for the study period (eg, leaving the area, pregnant or planning to become pregnant).

Written informed consent was obtained from each participant and the study was approved by the hospital's Institutional Review Board. Eligible participants were recruited from the CHC diabetes registry. Participants were randomly assigned to the CDMP intervention group (IC) or the attention control group (AC) by a fair coin toss.<sup>22</sup> The investigators, patients, and interventionists were not blinded to group assignment. Of the 67 patients who responded to study recruitment efforts, 46 were eligible and willing to participate. Of these, n = 25 were randomized to the IC and n = 21 were randomized to the AC (Figure 1).

The AC group received a diabetes education intervention consisting of seven 1-hour visits over a 12-month period

conducted by bicultural/bilingual clinic support staff trained to review a set of diabetes education booklets with the AC patients (ie, information on diet, medications, exercise, blood glucose monitoring, eye and foot care) that were published by the American Diabetes Association.<sup>23</sup> The AC interventionists encouraged patients to formulate diabetes-related questions for discussion with their primary care provider at the next scheduled primary care visit.

IC patients received seven 1-hour diabetes care visits over a 12-month period conducted by a bicultural/bilingual diabetes nurse and dietician team (both certified diabetes educators). For IC patients, CDMP data were uploaded from the host clinical information system or entered manually by interventionists using data templates to create active patient alerts and the 5 composite risk profiles. The CDMP database included vital signs, labs, medications, clinical

admissions, procedures, and diagnoses, which were summarized for the interventionists in the form of color-coded alerts (eg, laboratory values out of range), risk profiles (eg, high-risk cardiovascular disease, retinopathy, nephropathy, neuropathy, foot disease, poor glycemic control), and a 1-page clinical summary to communicate main findings with the primary care provider (electronically or in paper form placed in patient's chart). The DSCP assessment tool provided a 1-page summary of diabetes self-management behaviors and barriers to facilitate diabetes education discussion with patients during intervention sessions.

The CDMP team nurse contacted primary care providers to initiate or increase diabetes medications as needed, based on their experience and the clinical decision-making algorithms in the CDMP. The diabetes care team discussed the 1-page summary report generated by CDMP with the primary care providers by phone and a hard copy was placed in patient charts. Final medication adjustments were left up to the discretion of participants' providers based on clinical indications. Interventionists were well established professionally in the community health center and had strong prior collaborative relationships with the primary care providers taking part in the study.

The importance of culturally competent diabetes interventions has been established,<sup>24,25</sup> and cultural sensitivity was an important element of this intervention. Education materials and questionnaires were translated into Spanish, and the bicultural nurse and dietitian care management team assisted patients with reading/questionnaire completion to overcome numeracy, literacy barriers, and comprehension barriers. During the diabetes education sessions, dietary education focused on portion size, food selection, and cooking techniques for foods preferred by the local Hispanic population (predominately Puerto Rican).

## Study Measures

Demographic data (age, gender, marital status, income, education level, diabetes duration) were collected during the baseline research assessment period by medical chart review. Clinical data measured at baseline included A1C and blood pressure (BP; measured with an aneroid BP monitor after 5-minute resting period [minimum]). Frequency of diabetic foot screening and prophylactic aspirin use for cardiovascular risk reduction during the 1-year intervention period were obtained from study patients using a self-report questionnaire. Data on eye

exams and treatment received from local eye doctors during the study period were also obtained by self-report and follow-up with clinicians.

US Spanish versions of study questionnaires and educational materials were used and IC and AC interventionists assisted patients with reading or completing study assessments as needed to overcome barriers with literacy, numeracy, or comprehension. The 20-item Problem Areas in Diabetes (PAID) scale was used to measure diabetes-specific emotional distress (eg, complication fears, worry about treatment nonadherence, frustration, and other common emotions associated with psychological adjustment to diabetes).<sup>26–28</sup> Treatment satisfaction was measured with the Diabetes Treatment Satisfaction Questionnaire-Change version (DTSQ-C).<sup>29</sup> The PHQ-9 questionnaire was used to assess symptoms of depression over the previous 2 weeks. PHQ items reflect current DSM-IV criteria for major depressive disorder, such that a cut-point of 10 has 88% sensitivity and 93% specificity for correctly identifying patients with mild depression or greater.<sup>30–32</sup>

## Telemedicine Screening for Diabetes Retinopathy

Participants in the IC received a diabetes eye screening using the Diabetes Eye Care and Treatment (DECAT) program using the clinically validated Joslin Vision Network (JVN) protocol.<sup>33</sup> The DECAT is integrated into the CDMP system and provides for eye image capture in the primary care setting using a Topcon NW6S nonmydriatic retinal fundus camera set up in the intervention office without requiring the use of pharmacological pupil dilation. Nonsimultaneous stereo images were taken of 3 retinal fields (posterior pole, superior temporal, nasal) of each eye by a trained and certified JVN retinal imaging specialist who came to the clinical office. In addition to the 3 retinal fields a single external image of the eye was also obtained to evaluate lens, corneal, or eye lid abnormalities. The retinal images were evaluated for level of diabetic retinopathy at the JVN reading center located at the Joslin Diabetes Center, Boston, and then transmitted to the study researchers by secure email communication for dissemination to the patient's primary care provider.

## Statistical Analyses

Demographic and outcome variables were described using frequency distributions and appropriate summary statistics for central tendency and variability. Differences

Table 1  
Characteristics of Study Population at Baseline

	Attention Control Condition (n = 21)	Intervention Condition (n = 25)	<i>P</i> <sup>a</sup>
	Mean (SD)	Mean (SD)	
Age (years)	57.5 (9.5)	54.4 (10.4)	.31
Duration of diabetes (years)	13.8 (7.7)	10.3 (8.0)	.14
Body mass index (g/cm <sup>2</sup> )	35.8 (14.0)	33.8 (7.8)	.54
Hemoglobin A1C (%)	8.5 (1.0)	9.0 (1.2)	.13
Systolic blood pressure (mmHg)	143 (28)	132 (17)	.10
Diastolic blood pressure (mmHg)	81 (14)	80 (12)	.73
Diabetes distress <sup>b</sup>	44.3 (23.0)	54.2 (24.0)	.16
Female (%)	61.9%	68.0%	.67
Education: High school diploma or higher (%)	52.4%	28.0%	.09
Income: Under \$5,000 a year (%)	52.4%	36.0%	.26
Marital status: Not married or no partner (%)	33.3%	64.0%	.04
Depression <sup>c</sup> (%)	76.2%	56.0%	.15

<sup>a</sup>Based on analysis of variance for continuous variables and chi-square for categorical variables.  
<sup>b</sup>PAID: Problem Areas in Diabetes, scale 0 (no diabetes distress) to 100 (high diabetes distress).  
<sup>c</sup>Based on Patient Health Questionnaire-9; paper version used for control group, computer version for intervention group.

between groups at baseline and at follow-up were analyzed by parametric statistics (analysis of variance for continuous variables, chi-square or Fisher exact test for categorical variables). Changes in outcome variables from pre- to postintervention were analyzed as paired *t* tests for within-group changes. All analyses were performed using the Statistical Analysis System version 9.1 (SAS Institute, Cary, North Carolina).

## Results

The sample was 67% female with a mean (SD) age 55.8 (10.0) years and an average diabetes duration of 11.9 (7.9) years. Among participants who began the education program (ie, attended at least 1 education session), attendance to the diabetes education visits was high in both IC and AC groups (mean number of visits: 6.8 [0.7] and 5.9 [1.6], respectively, out of 7 scheduled). There were no differences between groups at baseline except for marital status ( $P = .04$ ) (Table 1).

There was a significant difference ( $P = .01$ ) between the IC and AC groups for change in blood glucose control: A1C decreased from 9.0% (1.3%) at baseline to 7.4% (1.4%) at 12 months in the IC group, and from 8.5% (1.0%) to 7.9 (1.4%) in the AC group (Table 2). There was a clinically significant reduction in diabetes distress in the IC group from baseline to 12 months, while diabetes distress increased in the AC group ( $P = .05$ ). Although more AC participants tended to report depression at baseline compared with IG participants ( $P = .15$ ), there was no difference in change in depression status from baseline to 12 months between the 2 groups ( $P = .56$ ). Diabetes treatment satisfaction tended to be higher for the IC group at the completion of the intervention ( $P = .06$ ).

The percentage of IC participants meeting the A1C goal (A1C < 7%) at 12 months was 45%, compared with 28% of AC participants ( $P = .27$ ; Table 3). Fifty-five percent of IC participants met the blood pressure goal (<130/80) at 12 months, compared with 28% of AC participants ( $P = .09$ ), and 65.0% of IC participants met the

Table 2

Comparison of Intervention and Attention Control Groups on Clinical and Behavioral Measures at 12-Month Follow-up

	Attention Control Condition (n = 18)	Intervention Condition (n = 21)	<i>P</i> <sup>a</sup>
	Mean (SD)	Mean (SD)	
Body mass index (g/cm <sup>2</sup> )	33.8 (6.9)	32.6 (6.3)	.60
Hemoglobin A1C (%)	7.9 (1.4)	7.4 (1.4)	.26
Change in hemoglobin A1C	-0.6 (1.1)	-1.6 (1.4)	.01
Systolic blood pressure	134.4 (21.6)	124.5 (15.1)	.11
Diastolic blood pressure	82.1 (9.2)	77.7 (9.9)	.17
Diabetes distress <sup>b</sup>	52.7 (26.3)	37.4 (26.4)	.08
Change in diabetes distress <sup>b</sup>	11.2 (37.6)	-14.4 (40.7)	.05
Treatment satisfaction <sup>c</sup>	33.8 (4.2)	35.7 (0.7)	.06
Depression <sup>d</sup>	38.9%	30.0%	.58
Change in depression status <sup>e</sup>	38.9%	35.0%	.80

<sup>a</sup>Based on analysis of variance for continuous variables and chi-square for categorical variables.  
<sup>b</sup>PAID: Problem Areas in Diabetes; scale: 0 (no diabetes distress) to 100 (high diabetes distress).  
<sup>c</sup>DTSQ-C: Change in Diabetes Treatment Satisfaction Questionnaire; scale: 0 (much less satisfied relative to baseline) to 36 (much more satisfied relative to baseline).  
<sup>d</sup>Based on a cut-point of 10 on the Patient Health Questionnaire-9 (PHQ-9); paper version used for control group, computer version for intervention group.  
<sup>e</sup>Percentage of patients who were depressed at baseline and not depressed at follow-up.

criteria for low diabetes distress (PAID < 50) compared with 33.3% of AC participants ( $P = .05$ ). At 12 months, the percentage of participants meeting the yearly eye screening goal was 91% in the IC and 78% in the AC ( $P = .27$ ), and 86% of participants in the IC met the yearly foot exam goal compared with 72% in the AC ( $P = .30$ ). Both groups reported 100% adherence to recommended aspirin therapy during the study.

Of the 25 patients originally recruited into the intervention group, 3 were nonadherent to the retinal imaging process. Of the remaining 22 patients who underwent retinal imaging, 4 had retinal images of poor quality that did not allow appropriate grading for diabetic retinopathy. Inability to grade the retinal images resulted in referral to an ophthalmologist for a dilated eye examination. A total of 7 patients had no diabetic retinopathy. Of these 7 patients, 1 exhibited mild cataracts and a second exhibited a cup/disc asymmetry that was potentially an indicator of glaucoma risk requiring referral to an ophthalmologist. A total of 8 patients exhibited mild or moderate nonproliferative diabetic retinopathy. Of these 8, 1 patient exhibited clinically

significant macula edema, 2 exhibited diabetic macula edema that was not clinically significant, and 1 patient had a branch retinal artery occlusion in both eyes. These later conditions required referral to an ophthalmologist for dilated eye examination. One patient was diagnosed with severe nonproliferative diabetic retinopathy with macula edema that was not clinically significant, requiring referral to an ophthalmologist for dilated eye examination. Two patients were diagnosed with proliferative diabetic retinopathy, 1 with less than high risk characteristics and clinically significant macula edema, and the other with greater than high risk characteristics with clinically significant macula edema and evidence of vitreous hemorrhage. Both these patients required referral to ophthalmology for potential pan retinal laser photocoagulation treatment.

## Discussion

The results of this 7-session, 1-year diabetes care intervention for Hispanic T2DM patients using the CDMP model demonstrated that, compared with an attention

Table 3  
Percentage of Patients Meeting Clinical Goals at Follow-up

	Attention Control Condition (n = 18)	Intervention Condition (n = 21)	<i>P</i> <sup>a</sup>
	Mean (SD)	Mean (SD)	
Hemoglobin A1C < 7.0%	27.8%	47.6%	.20
Blood pressure < 130/80 mmHg	27.8%	55.0%	.09
Diabetes distress <sup>b</sup> < 50	33.3%	65.0%	.05
Foot exam during study year	72.2%	85.7%	.30
Eye exam during study year	77.8%	90.5%	.27
Regular aspirin use	100.0%	100.0%	1.00

<sup>a</sup>Based on analysis of variance for continuous variables and chi-square for categorical variables.  
<sup>b</sup>PAID: Problem Areas in Diabetes; scale: 0 (no diabetes distress) to 100 (high diabetes distress).

control condition, there was a significant reduction in mean A1C level and patient-reported diabetes distress, high treatment satisfaction, and a clinically important improvement in the percentage of patients meeting recommended treatment goals for blood glucose and blood pressure control, and annual eye and foot exams. These findings and the high participation rates of patients and providers show that our culturally sensitive intervention involving a bicultural/bilingual diabetes care team (nurse and dietitian) was not only clinically effective, but also feasible and acceptable to poorly controlled Hispanic patients attending a community health center. It was also well received by their primary care providers who collaborated with the diabetes care team to deliver a comprehensive diabetes program within a busy primary care clinic setting.

The CDMP intervention included a strong component of cultural sensitivity to meet the needs of the Hispanic, predominantly Puerto Rican, population. This sensitivity included accommodation for Spanish language preference in conversation and reading materials, consideration of Hispanic cultural habits around food and eating, and the importance of the family context in shaping diabetes care decisions. While Puerto Ricans represent the second largest Hispanic population in the United States, Mexicans are by far the largest Hispanic subgroup, and groups from Central and South America are also well represented.<sup>34</sup> While these groups do differ in terms of their culture, language, degree of acculturation in the US, and other

factors,<sup>17</sup> the culturally sensitive strategies used in the CDMP intervention can be adapted to accommodate the specific needs of different Hispanic subgroups, as well as non-Hispanic populations. Several of the strategies implemented in this study (eg, Hispanic cultural focus, bicultural nurse/dietician team model) have been used successfully in a prior community-based chronic care management intervention for Hispanic (predominately Mexican) diabetes patients, and were associated with a significant decrease in A1C ( $P < .01$ ) and was accompanied by an increase in patient satisfaction level ( $P < .01$ ).<sup>35</sup>

The intervention also involved the use of innovative health information technology that facilitated more convenient diabetic eye screening based in the primary care setting, automated the diabetes self-management education assessment process that freed up time for education and support, provided clinical decision-making support based on evidence-based guidelines, and allowed timely and structured communication with the patient's primary care providers on medication intensification and other salient clinical issues. The comprehensive diabetes care intervention successfully targeted factors contributing to clinical inertia that commonly impacts minority and low socioeconomic status diabetes populations.<sup>6,36</sup>

The computerized self-management assessment tool (DSCP) integrated into CDMP provided an efficient (10 minute) assessment that identified diabetes-related behavioral and psychosocial barriers and provided the



structure for tailored diabetes education sessions through its 1-page summary of patient-reported behaviors and self-management barriers. While this interactive, Web-based tool may be used by patients independently, for the current intervention case managers were on hand to assist patients and administered the Web-based questionnaires using an interview format (ie, questions were read out loud to patients by the bicultural/bilingual diabetes care team). This was done to ensure consistent use of the tool throughout the intervention population, as it was anticipated that patients would be uncomfortable using the tool on their own. Our results showed that the CDMP intervention reduced the emotional burden of living with diabetes (ie, diabetes distress) for intervention patients as compared to attention control. These findings are consistent with our recent meta-analysis, which showed that diabetes self-management interventions have a significant beneficial impact on diabetes distress levels<sup>37</sup> and that diabetes distress is more closely related to metabolic control than depression.<sup>38,39</sup>

It is notable that research funding to date for the CDMP, including its diabetes eye telemedicine network (DECAT), has come from federal sources (ie, US Department of Defense and National Institutes of Health). Thus, the CDMP technology platform, which is built using open source technologies, is available license-free to federally qualified health centers. These centers currently serve a population that includes 33% Hispanics and includes a large network of 1200 CHCs serving medically underserved areas or populations.<sup>40</sup> The diabetes eye telemedicine component of CDMP (DECAT) has been well validated in prior research and is associated with better diagnostic outcomes at lower costs compared with conventional eye examinations conducted in the clinic for sight-threatening proliferative diabetes retinopathy.<sup>41-43</sup> There are currently 6 clinical sites actively using the CDMP program in the United States and 60 sites participating in the DECAT eye telemedicine program as a stand-alone system, but no published outcomes data have been available before this study. In addition, state governments are taking advantage of available technologies for diabetes care, including Web-based training, tools for chronic care management, and advancing availability of screening for diabetic retinopathy.<sup>44</sup>

There are limitations to the current analysis which should be considered in interpreting the study findings. First, the diabetes educators in the intervention condition trained and supervised the attention control clinical staff. While it is possible that this may have introduced

contamination between intervention and attention control conditions, the clinical staff delivering the attention control sessions were not trained diabetes educators and their contact with the interventionists was limited to instructions regarding appropriate use of the ADA education materials provided in the attention control condition. Also, any such contamination would likely have resulted in an underestimation of the findings of this study. Second, the small sample size in this study resulted in a lack of power to detect statistically significant differences between study conditions for several clinical outcomes (eg, percentages of patients meeting treatment goals at 12 months). However, the fact that change in A1C was statistically significant at  $P < .01$  (despite the small sample size) strengthens the conclusion that the intervention did have a large impact on A1C.

This analysis demonstrates the clinical usefulness of a 1-year, culturally sensitive, comprehensive diabetes care intervention for Hispanic patients with poorly controlled T2DM attending an urban community health center. In addition to demonstrating that the CDMP intervention was effective in helping patients meet evidence-based guidelines for diabetes care, this analysis also shows that the intervention is feasible and acceptable to Hispanic patients with poorly controlled T2DM attending a community health center.

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