# Managing the Space between Visits: A Randomized Trial of Disease Management for Diabetes in a Community Health Center

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**BACKGROUND:** Diabetes outcomes are worse for underserved patients from certain ethnic/racial minority populations. Telephonic disease management is a cost-effective strategy to deliver self-management services and possibly improve diabetes outcomes for such patients.

**OBJECTIVE:** We conducted a trial to test the effectiveness of a supplemental telephonic disease management program compared to usual care alone for patients with diabetes cared for in a community health center.

**DESIGN:** Randomized controlled trial.

**PARTICIPANTS:** All patients had type 2 diabetes, and the majority was Hispanic or African American. Most were urban-dwelling with low socioeconomic status, and nearly all had Medicaid or were uninsured.

**MEASUREMENTS:** Clinical measures included glycemic control, blood pressure, lipid levels, and body mass index. Validated surveys were used to measure dietary habits and physical activity.

**RESULTS:** A total of 146 patients were randomized to the intervention and 149 to the control group. Depressive symptoms were highly prevalent in both groups. Using an intention to treat analysis, there were no significant differences in the primary outcome (HbA1c) between the intervention and control groups at 12 months. There were also no significant differences for secondary clinical or behavioral outcome measures including BMI, systolic or diastolic blood pressure, LDL cholesterol, smoking, or intake of fruits and vegetables, or physical activity.

**CONCLUSIONS:** A clinic-based telephonic disease management support for underserved patients with diabetes did not improve clinical or behavioral outcomes at 1 year as compared to patients receiving usual care alone.

 $\it KEY\ WORDS:$  diabetes; self-management; telehealth; disease management; community health centers; Hispanic Americans.

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Funded by a grant from the Connecticut Health Foundation. Received December 15, 2009 Revised April 27, 2010 Accepted May 19, 2010 Published online June 16, 2010 D isease management can improve chronic disease outcomes and reduce health care costs. Currently, 96% of the top 150 commercial payers provide some form of disease management services to their patients<sup>1</sup>. Published reviews on the impact of such programs for diabetes have been mixed<sup>1,2</sup>.

Diabetes affects the poor and members of ethnic/racial minorities at a higher rate than other groups<sup>3–5</sup>. These populations have worse adherence to self care<sup>6,7</sup>, worse diabetes control, and higher rates of serious diabetes-related complications<sup>8</sup>. Adherence to a diabetes treatment regimen can be daunting for the most health-literate and motivated patient. For some, such as the poor, the depressed, the low literate, or the non-English speaker, it can be even more challenging.

Disease management, emphasizing self-management, adherence, and frequent contact outside the medical setting, would seem to be ideally suited to improve outcomes for underserved patients with diabetes. To test this hypothesis, we designed a telephonic diabetes disease management protocol in a Community Health Center. This program was implemented within the health center, using health center staff directly connected through an electronic health record to the primary care team. The intervention was tailored to meet the cultural and linguistic needs of a medically underserved, predominantly Hispanic population.

# **METHODS**

**Design.** "Managing the Space Between Visits" (MSBV) was a randomized, controlled trial of telephonic disease management for underserved, largely Hispanic/Latino patients cared for in a Community Health Center. The unit of randomization was the patient. The study was reviewed and approved by Chesapeake Institutional Review Board.

Setting. The Community Health Center, Inc. (CHC), is the largest Federally Qualified Health Center in Connecticut, providing services to approximately 50,000 patients in multiple communities across the state. Forty-three percent of the patients are Hispanic, and 13% are African American. Nearly half speak a language other than English at home. Eighty-eight percent are at or below 200% of the poverty level,

Level 1	HbA1c ≥9	Weekly calls
	OR	
	HbA1c <9 and Stage 2 HTN	
Level 2	7< HbA1c <9	Biweekly calls
	or	
	HbA1c ≤7	
	With:	
	Stage 1 HTN,	
	Depression (PHQ9 $\geq$ 10),	
	diabetes neuropathy,	
	nephropathy, or	
	retinopathy	
Level 3	HbA1c ≤ 7	Monthly calls

Figure 1. Call frequency.

and 25% have no medical insurance. Primary medical care is provided by internists, family practitioners, pediatricians, and nurse practitioners. Onsite mental health, podiatric, and dental care are available. The intervention was conducted from a centralized call center and was offered to patients with type 2 diabetes at the two largest CHC clinics. Both clinics are similar in size, services, and setting.

Staff. Specialized nurses were trained to provide the intervention by a consultant with experience in the commercial disease management industry. Self-management training was conducted by a "master trainer" in the Chronic Disease Self-Management Program from Stanford University. The nursing staff conducted the calls from a call center or from home using a Virtual Private Network (VPN) connection link to the EHR. Patient enrollment and data collection were managed by a research assistant not involved in the provision of the intervention.

**EHR.** Nurses documented their telephone encounters in the patient's electronic medical record. Templates allowed real-time documentation. Notes were forwarded to the primary care provider for co-signature.

Enrollment. All patients with type 2 diabetes age 18 and over from the two participating sites were eligible for the study. Patients were excluded if they were (1) unwilling/unable to give informed consent, (2) spoke primarily a language other than English or Spanish, (3) did not have a telephone, (4) were active substance abusers, or (5) had a mental or physical impairment that would prevent them from engaging in the calls or in diabetes self-management activities. Using a list generated from the practice management system, the research assistant attempted to contact all eligible patients by letter and/or telephone and invite them to participate in the study. Those interested scheduled an appointment with the research

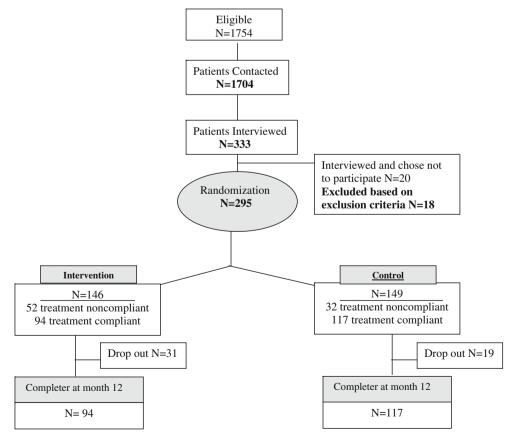


Figure 2. Flowchart for enrollment, randomization, and follow-up of study participants.

Table 1. Demographic and Clinical Characteristics Across Treatment Group

Characteristic	Treatment group		
	Control (N=149) <sup>b</sup>	Intervention (N=146) <sup>b</sup>	
Gender			0.747
Female	85 (57.1)	86 (58.9)	
Male	64 (43.0)	60 (41.1)	0.750
Race Black	12 (8.1)	15 (10.3)	0.750
White	39 (26.2)	40 (27.4)	
Other	98 (65.8)	91 (62.3)	
Marital status			0.820
Not married	93 (62.4)	93 (63.7)	
Married	56 (37.6)	53 (36.3)	0.405
Education	42 (00.1)	20 (01 0)	0.425
0–6 7–8	43 (29.1) 20 (13.5)	32 (21.9) 19 (13.0)	
9–12	71 (48.0)	75 (51.4)	
≥13	14 (9.5)	20 (13.7)	
DE education			0.963
No	47 (31.8)	46 (31.5)	
Yes	101 (68.2)	100 (68.5)	
Language		00 (5 = -)	0.619
Either	21 (14.1)	23 (15.8)	
English Spanish	37 (24.8)	42 (28.8)	
Spanish Insurance	91 (61.1)	81 (55.5)	0.693
SAGA	20 (13.4)	18 (12.3)	0.033
Medicaid	60 (40.3)	66 (45.2)	
Other	69 (46.3)	62 (42.5)	
CAD			0.812
No	127 (85.2)	125 (86.2)	
Yes	22 (14.8)	20 (13.8)	
CHF	145 (05.0)	1.40 (07.0)	0.977
No Voc	145 (97.3)	142 (97.3)	
Yes COPD	4 (2.7)	4 (2.7)	0.794
No	143 (96.0)	140 (96.6)	0.734
Yes	6 (4.0)	5 (3.5)	
Asthma			0.462
No	123 (82.6)	114 (79.2)	
Yes	26 (17.4)	30 (20.8)	
Hypertension	00 (0 4 0)	00 (00 0)	0.686
No	36 (24.2)	38 (26.2)	
Yes	113 (75.8)	107 (73.8)	0.680
Past depression No	74 (49.7)	69 (47.3)	0.000
Yes	75 (50.3)	77 (52.7)	
Current depression	10 (0010)	(==,	0.996
No	97 (65.1)	95 (65.1)	
Yes	52 (34.9)	51 (34.9)	
Clinically diagnosed depression	00 (	00 (57 -:	0.388
No Voc	99 (66.9)	90 (62.1)	
Yes Current smoker	49 (33.1)	55 (37.9)	0.440
No	119 (80.4)	112 (76.7)	0.440
Yes	29 (19.6)	34 (23.3)	
Depression (screening)	_= (10.0)	5 - (20.0)	0.752
No	112 (75.7)	112 (77.2)	
Yes	36 (24.3)	33 (22.8)	
Ethnicity			0.942
Central American	1 (0.7)	1 (0.7)	
Mexican	8 (5.4)	6 (4.1)	
Puerto Rican	98 (65.8)	90 (61.6)	
South American Other Hispanic	1 (0.7) 8 (5.4)	1 (0.7) 9 (6.2)	
Other Hispanic Other	33 (22.2)	9 (6.2) 39 (26.7)	
	00 (22.2)	00 (20.1)	0.585
Insurance			

(continued on next page)

Table 1. (continued)

Characteristic	Treatment g	pc		
	Control (N=149) <sup>b</sup>	Intervention (N=146) <sup>b</sup>		
Medicare	34 (22.8)	28 (19.2)		
Medicare/Medicaid	3 (2.0)	7 (4.8)		
SAGA	20 (13.4)	18 (12.3)		
Private	9 (6.0)	5 (3.4)		
Self	22 (14.8)	22 (15.1)		
Dual eligible	1 (0.7)	0 (0)		
Disenrolled			0.007	
No	117 (78.5)	94 (64.4)		
Yes (list below)	32 (21.5)	52 (35.6)		
Communication barrier	0 (0)	1 (1.9)		
Death or terminal illness	1 (3.1)	2 (3.9)		
Limited tel. contact	1 (3.1)	23 (44.2)		
Mental health	1 (3.1)	1 (1.9)		
Moved	0 (0)	1 (1.9)		
No 6-month follow-up	17 (53.1)	2 (3.9)		
No phone contact	0 (0)	4 (7.7)		
No longer CHC patient	3 (9.4)	9 (17.7)		
Not adherent to lab protocol	5 (15.6)	5 (19.6)		
Patient choice	4 (12.5)	2 (3.9)		
Other	0 (0)	2 (3.9)		

<sup>&</sup>lt;sup>a</sup>Table values are n (column %) for categorical variables

Note: In the Race category, we have collapsed mixed and Asian into the Other groups; in the Marital Status category, we have collapsed Divorced, Separated, Single, Single with partner and widow into the group of Not Married; Other insurance including Medicare, Private, Self, Dual eligible, Medicare/Medicaid; there is one case in the Asthma category with the value 'o' that was assumed to be a typo and was changed to 'No.' Past depression = patient endorsing the question "have you ever been treated for depression?" Current depression = patient endorsing the question "are you currently being treated for depression?" Clinical diagnosed depression = current diagnosis of depression in the patient's medical record

assistant. Those who remained interested after the information session signed an informed consent. All patients in the study received a \$25 gift card to a local store after completing their 6-and 12-month assessments. Patients were considered lost to follow-up if they transferred care to another location, could not be contacted by telephone after three attempts, or failed to return for their 6- or 12-month assessments.

**Randomization.** Once enrolled, patients were block randomized in groups of four by a computerized algorithm to receive the intervention plus usual care or usual care alone. Patients randomized to usual care continued to receive primary care at CHC.

**Assessment.** Patients were assessed at intake, 6 months, and 12 months into the study. Baseline demographic information was collected at intake. Patients rated their overall health as excellent, very good, good, fair, or poor. The presence of depressive symptoms was assessed using the Patient Health Questionnaire-9 (PHQ-9)<sup>9</sup>. Validated surveys in English and Spanish were used to assess dietary habits and physical activity, the Brief Dietary Assessment <sup>10</sup>, and the Rapid Assessment of Physical Activity (RAPA)<sup>11</sup>, respectively. Height, weight, blood pressure, lipid levels, and hemoglobin A1C levels were measured at each assessment.

<sup>&</sup>lt;sup>b</sup>Percentages may not sum to 100% due to rounding

 $<sup>^{\</sup>rm c}\text{P-value}$  is from  $\chi^2$  test (categorical variables) or from Fisher's exact test if marked with #

Intervention. Patients in the intervention received 1 year of telephonic disease management. Call content was semi-structured. Calls were unscripted, allowing the nurse to address each patient's individual needs, whether related to diabetes or other topics. Nurses had wide latitude to discuss the topics raised by the patient while also covering the following items in a more structured fashion:

- 1. brief clinical assessment
- self-management: including diet, exercise, stress reduction, smoking cessation, readiness assessment, and development of specific self-management goals
- medication adherence: problem solving to help improve adherence
- glucose monitoring and review of home glucose monitoring results

Intervention fidelity was monitored by chart review conducted by the project coordinator.

Patients were called weekly, bi-weekly, or monthly depending on their risk stratification (Fig. 1). Patients could be reassigned to receive more or fewer calls if their risk stratification changed at the 6-month assessment or if the patient requested a change in call frequency. Nurses also mailed educational materials to patients covering various topics discussed during the calls. This material was in English and Spanish, and at a fourth grade reading level.

Statistical Methods. Analysis was based on the intention-totreat principle with subjects analyzed in the group to which they were randomized and the modified intent-to-treat analysis population with at least one post randomization HbA1c measure. An enrollment target was made based on power calculations to detect a change in hemoglobin A1C of 0.7 or more. Two hundred seventy-four patients (with 137 in each arm) in total were sufficient to detect a minimum difference in mean changes of 0.7% in HbA1c at 80% power and 5% significance level assuming standard deviations of 2.1% for HbA1c. The total recruitment of 300 patients was needed to account for 10% loss to follow-up. Baseline characteristics were compared between intervention groups using either a Pearson's chi-square test or Fisher's exact test for categorical data, and a Wilcoxon rank sum test or Student's t test for ordinal or continuous data, respectively.

For the analysis of the primary outcome, HbA1c, a mixedmodel repeated-measures analysis of covariance (implemented with the use of SAS PROC MIXED), was used to compare intervention groups at each assessment point (months 6 and 12)<sup>12</sup>. Models included fixed effects for intervention, time, and their interaction, as well as baseline HbA1c. Residual correlation from repeated measures was accounted for by an unstructured covariance pattern. This analysis assumes that missing data were missing at random (i.e., missing values may be dependent on observed but not on unobserved data) and is more robust than other alternatives such as Last Observation Carried Forward  $(LOCF)^{13}$ . Sensitivity analyses were also performed using LOCF, which produced similar conclusions and thus are not presented. Ad hoc subgroup analyses were also performed to determine whether the impact of the intervention was modified by initial HbA1c category, current depression, Spanish speaking only, and lower education level. The interaction test between intervention and these potential moderators was performed.

Secondary clinical or behavioral outcome measures, including BMI, systolic or diastolic blood pressure, and LDL cholesterol, were also assessed with the use of mixed-model repeated-measures analysis of covariance. Generalized estimating equations (GEE) with a negative binomial distribution were used to compare the intake of fruits and vegetables. For the perceived health status and physical assessment outcomes, GEE cumulative logit regressions with the assumption of proportional odds were used to compare intervention groups. Data across all post-randomization measurement times were used with adjustment for baseline values as a covariate.

Analyses were performed with the use of SAS software, version 9.1.3 (SAS Institute, Cary, NC). All comparisons were planned, and tests were two-sided. A P value of less than 0.05 was considered to indicate statistical significance.

### **RESULTS**

From 1,754 patients with type 2 diabetes potentially eligible for the study, 297 signed an informed consent, and 146 were randomized to receive the intervention and 149 to the control

Table 2. Baseline Outcome Measures Comparison between Two Groups

Outcome	Treatment group		
	Control (N=149) <sup>b</sup>	Intervention (N=146) <sup>b</sup>	
Clinical outcomes			
HbA1c(average)	$8.4 \pm 2.33$	$7.6 \pm 1.75$	0.006*
HbA1c <7	48 (33.6)	67 (46.5)	
7≤ HbA1c<9	50 (35.0)	51 (35.4)	
HbA1c >9	45 (31.5)	26 (18.1)	
Systolic blood pressure	$133.1 \pm 19.55$	132.6±19.30	0.845
Diastolic blood pressure	$77.1 \pm 14.24$	$78.3 \pm 12.49$	0.445
BMI	$33.7 \pm 6.64$	$35.4 \pm 8.63$	0.055
BMI <25	7 (4.7)	13 (8.9)	0.153
25≤ BMI<30	43 (28.9)	31 (21.2)	
BMI ≥30	99 (66.4)	102 (69.9)	
Cholesterol	173.9±42.29	169.6±47.4	0.421
LDL	94.8±36.11	89.5±35.66	0.225
HDL	46.83±13.04	$46.1 \pm 12.64$	0.644
Triglycerides	167.8±88.11	169.7±108.3	0.594*
Behavior outcomes			
Physical assessment			0.900
Sedentary	50 (33.6)	44 (30.1)	
Under-active	7 (4.7)	9 (6.2)	
Under-active light	11 (7.4)	12 (8.2)	
Under-active regular	23 (15.4)	27 (18.5)	
Active	57 (38.3)	54 (37.0)	
Nutrition outcomes			
Fat intake			0.599
Excellent	115 (77.7)	111 (76.0)	
Good	26 (17.6)	24 (16.4)	
Fair	7 (4.7)	11 (7.5)	
Fruit/vegetable intake	$2.4 \pm 1.32$	$2.7 \pm 1.52$	0.071
(average per day)			
0–2/day	82 (55.4)	71 (48.6)	0.398
3–4/day	55 (37.2)	59 (40.4)	
≥5/day	11 (7.4)	16 (11.0)	
-	N=50	N=55	
PHQ9	12.5±5.99	11.09 (5.42)	0.202

 $<sup>^{</sup>a}$ Table values are mean  $\pm$  standard deviation for continuous variables and n (column %) for categorical variables

<sup>&</sup>lt;sup>b</sup>Percentages may not sum to 100% due to rounding

 $<sup>^</sup>c$ P-value marked with \* are from Wilcoxon test, otherwise from Student's t-test for continuous variables and  $\chi^2$  test for categorical variables

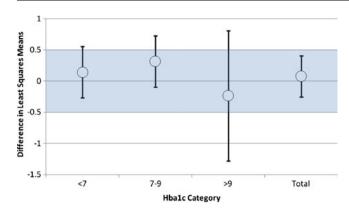


Figure 3. Overall and baseline HbA1c group-specific treatment differences and 95% confidence intervals for HbA1c. Differences in least squares means between control and intervention at 12 months with 95% confidence intervals for the overall treatment effect and the treatment effect for subgroups of baseline HbA1c. The band represents a clinically important difference in HbA1c of ±0.50%.

group. Figure 2 shows details of the selection process. There were no significant differences in the two groups at baseline with regard to sociodemographic variables. However, the control group had a significantly higher baseline average HbA1c than the intervention group  $(8.4\pm2.33~\text{vs.}~7.6\pm1.75,~p=0.006)$ . All other clinical variables were similar between the two groups (Tables 1 and 2). Of those patients who were randomized, 115 (79%) in the control and 94 (64%) in the intervention group completed the 1-year study. The most common reason for not completing the study was the patient's being lost to follow up.

**Evaluation of Intervention on HbA1c.** After adjusting for differences in baseline HbA1c, we found no significant difference in the primary outcome (HbA1c) between the intervention and control groups at 12 months based on the modified intention to treat analysis population [control-intervention 0.083 (-0.25, 0.41)] (Fig. 3 and Table 3). The confidence interval for the treatment difference was consistent with the absence of a clinically relevant intervention benefit (i.e., 0.5 or greater). Analyses by baseline HbA1c group demonstrated no significant difference in the effect of the treatment across these subgroups (Fig. 3, p=0.989). Group differences at 12 months were: 0.14, (-0.27, 0.56), p=0.50; 0.32, (-0.10, 0.73), p=0.14; and -0.23, (-1.28, 0.81), p=0.66

in those with good (Hba1c <7.0), moderate (Hba1c 7.0–9.0) and poor (Hba1c >9.0) control at baseline, respectively.

**Evaluation of Intervention on Secondary Outcomes.** No significant differences were observed between the intervention and control group at 12 months for secondary clinical or behavioral outcome measures (Table 3). In addition, perceived health status and self-reported rates of physical activity did not vary between treatment and control groups (Table 4).

**Subgroup Analyses.** Additional sub-group analyses were performed to determine whether patients with depression, Spanish speakers, or those with lower educational attainment were more likely to benefit from the intervention (Table 5). None of the interactions between intervention and these potential moderators was significant (p=0.4, 0.27 and 0.91 respectively). Patients with an established diagnosis of depression did show a trend towards benefit after 12 months of intervention, but this finding did not achieve statistical significance.

## **DISCUSSION**

This telephonic disease management intervention for underserved patients with diabetes showed no significant benefit on a wide variety of primary and secondary clinical and behavioral outcomes. Interval estimates for the primary outcome variable, glycemic control, excluded a clinically significant difference in HbA1c. While not powered to evaluate subgroups, our analysis did not find variation in HbA1C results based on baseline glycemic control.

There are several possible explanations for the lack of treatment effect. It is possible that the 1-year duration was insufficient to realize benefits from an intervention geared at promoting lifestyle changes. Such changes may take time to enact and show benefit, and HbA1c lags behind actual improvement. However, commercial disease management providers have claimed that such benefits accrue rapidly, with interventions similar in design to our own.

The inclusion of medication management and titration might have strengthened the impact of the intervention. We chose to emphasize medication adherence rather than medication management based on our hypothesis that poor adherence was more critical to improving diabetes care in a population already well managed by the primary care providers.

Table 3. Comparison of Clinical/Behavioral Outcomes between Treatment Groups at Month 6 and Month 12 (Data Are Expressed as Least Squares Means)

Month 6 (N=256)				Month 12(N=245)		
Outcome	Control	Intervention	Treatment difference (95% CI)	Control	Intervention	Treatment difference (95% CI)
HbA1c	7.64	7.66	-0.01(-0.34,0.31) P=0.94	7.74	7.66	0.08(-0.25,0.41) P=0.63
BMI	34.63	34.58	0.05(-0.4,0.50) P=0.82	34.69	34.50	0.19(-0.46,0.84) P=0.56
DBP	79.3	79.2	0.07(-2.7,2.8) P=0.96	78.3	78.2	0.13(-2.4,2.7) P=0.92
SBP	137.1	136.6	0.5(-4.2,5.2) P=0.83	134.7	133.2	1.47(-3.04,5.98) P=0.53
LDL	89.57	92.92	-3.35(-10.76,4.06) P=0.38	85.31	89.48	-4.16(-11.12,2.80) P=0.24
Fruits/vegetables	2.58	2.70	<sup>a</sup> 0.96(0.84,1.08) P=0.49	85.31	89.48	<sup>a</sup> 1.02(0.88,1.16) P=0.73

<sup>&</sup>lt;sup>a</sup>Ratio of control to intervention mean

Table 4. Comparison of Health Status and Physical Assessment between Treatment Groups at Month 6 and Month 12 (Data Are Expressed as Odds Ratios)

	Month 6	Month 12		
Outcome	Odds ratio (control/intervention)	Odds ratio (control/intervention)		
Perceived health status Physical assessment	1.07 (0.65, 1.74) P=0.80 0.83 (0.50, 1.35) P=0.45	1.58 (0.92, 2.7) P=0.10 0.93 (0.54, 1.61) P=0.80		

We chose to enroll patients with all levels of glycemic control. Several successful diabetes disease management trials in different settings from ours have focused on patients with elevated HbA1Cs<sup>14–16</sup>. This decision was made due to uncertainty as to which patients might benefit most from disease management. Patients with good control may be the most motivated to learn self-management skills and better maintain control over time. Alternatively, those with the highest HbA1C might have the most need for disease management but be less motivated or able to engage in self-management.

Patients in both the intervention and the control received high quality "usual" diabetes care, likely superior to that found in many other primary care settings. Usual care included access to diabetes education and self-management, a well-trained, bilingual staff, use of an electronic health record, and strong organizational structure emphasizing quality, continuity, and access. It is possible that an intervention such as this would be more beneficial to patients without access to this level of "usual care."

It also may be that our intervention was not integrated enough with primary care. Our call center was physically removed from the clinical areas, and nurses did not have face-to-face or scheduled contact with patients, providers, and care teams. The Medicare Care Coordination demonstrations project suggested that substantial face-to-face contact in addition to telephonic contact was needed to improve outcomes <sup>17</sup>. Rothman et al. <sup>14</sup> showed improved intermediate diabetes outcomes in underserved patients with an intervention emphasizing intensive face-to-face support from pharmacists and case managers.

Nearly 35% of the patients carried a diagnosis of depression, and just over 50% had a history of depression. Patients with diabetes and depressive symptoms have worse adherence to self-care guidelines<sup>6.7</sup>, glycemic control, and higher rates of

diabetic complications <sup>18–20</sup>. Although patients had access to on-site mental health services in both the intervention and control, the intervention itself was not designed to manage depression.

The higher dropout rate in the intervention group could have biased the treatment comparison. However, in this case it is unlikely that the higher dropout rate in the intervention group resulted in the treatment effect equivalence as this requires those dropouts in the intervention group to be the ones improving with intervention. The baseline HbA1c was compared between individuals who dropped out and those were not lost to follow-up, and no significance was found (8.0  $\pm$  2.03 in those not lost to follow-up vs. 8.08  $\pm$  2.44 in those who dropped out).

Randomization failed to achieve an even distribution between groups with regard to HbA1C. This effect was most pronounced in the subgroup with HbA1C>9, which might have been expected to benefit most from the intervention. While appropriate statistical adjustments were made to account for these baseline differences, this inequity remains a limitation of the study.

The program was grounded on the principals of empowerment and self-management, which have been shown to improve diabetes outcomes in diverse populations  $^{21-28}$ . The flexible approach taken by the nurses over the phone in using these techniques was a strength, but also a weakness, making it more difficult to evaluate or replicate. Primary care in a community setting requires a great deal of adaptability to changing circumstances. We chose to embed this concept in the telephonic intervention to give the nurse maximum latitude to address patients' specific needs, even if they were outside the realm of diabetes care. In so doing, it was not possible to assess the fidelity of the intervention through checklists or process measures. We specifically chose to avoid checklists for fear that it would inhibit the nurse from addressing each patient's needs in a patient-centered rather than disease-centered manner.

Lack of blinding of the primary care providers and the presence of control and intervention patients in the same clinics were additional weaknesses, which may have led to contamination.

In summary, our randomized controlled trial provided telephonic disease management to underserved, largely Spanish-speaking patients with diabetes. Despite a strong emphasis on cultural and linguistic competence, a flexible, telephone-based intervention, and use of a common electronic health record to link providers with call center nurses, the

Table 5. Subgroup analysis

-		Month 6			Month 12				
Outcome	Subgroup	Control	Intervention	Treatment difference (95% CI)	Control	Intervention	Treatment difference (95% CI)		
HbA1c	Current depression								
	Yes	7.76	7.85	-0.09 (-0.64, 0.46) p=0.75	8.21	7.77	0.44(-0.11, 0.99) P=0.12		
	No	7.58	7.57	0.01 (-0.38, 0.40) p=0.97	7.47	7.61	-0.14(-0.55, 0.27) P=0.52		
	Education								
	High	7.61	7.65	-0.04 (-0.46, 0.38) p=0.85	7.74	7.60	0.14(-0.30, 0.57) p=0.54		
	Low	7.69	7.67	0.02 (-0.50, 0.54) p=0.93	7.75	7.75	0.00(-0.52, 0.52) p=0.99		
	Spanish speaking								
	Yes	7.59	7.69	-0.10 (-0.52, 0.32) p=0.65	7.66	7.75	-0.10(-0.53, 0.33) p=0.65		
	No	7.73	7.61	0.12 (-0.41, 0.64) p=0.66	7.88	7.52	0.35(-0.17, 0.88) p=0.18		

intervention did not improve glycemic control or a wide range of other clinical and behavioral outcomes. While the need for new strategies to control the growing diabetes epidemic among underserved, minority populations is great, it is unclear whether telephonic disease management can provide the answer.

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