FEATURE ARTICLE

Impact of Monthly A1C Values Obtained at Home on Glycemic Control in Patients With Type 2 Diabetes: A Randomized Clinical Trial

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The purpose of this randomized controlled clinical trial was to determine whether an A1C value obtained at home by participants followed by a phone discussion of the result with a clinician would lead to *1*) a more rapid and significant decrease in A1C, *2*) more effective advancement of diabetes treatment, and *3*) improvement in diabetes self-care behaviors. The study included 307 participants with type 2 diabetes, most of whom were of Latino origin. All study participants experienced a statistically significant reduction in mean A1C (control subjects −0.3%, $P = 0.04$; intervention subjects −0.5%, $P = 0.0002$), but there was a statistically significant difference in the number of people who achieved a reduction of ≥0.5% by 6 months, favoring the intervention (33.6 vs. 46.7%, $P = 0.05$).

Type 2 diabetes is the most common form of diabetes. In the United States, >30.3 million people live with diabetes, representing 9.4% of the population (1). The American Diabetes Association Standards of Care recommend using A1C to assess glycemic control in patients with diabetes (2). According to these guidelines, a reasonable A1C goal for most adults with type 2 diabetes is <7% (2). It is recommended that health care providers perform this test quarterly; however, based on clinical judgment, the frequency of testing can change. Based on data from the National Health and Nutrition Examination Survey 2013–2016, the prevalence of having an A1C <7% in the general U.S. population with diabetes increased from 43 to 55.8% (3).

A1C values aid in medical decision-making regarding advancing diabetes therapy. Point-of-care (POC) A1C testing has been found to improve diabetes control and had a greater impact in people with a higher initial A1C (4).

We hypothesized that A1C values measured at home by patients and then discussed with a clinician via phone would lead to *1*) a more rapid and significant decrease in A1C, *2*) more effective advancement of diabetes treatment, and *3*) improvement in diabetes self-care behaviors. To test this hypothesis, we performed a trial comparing the effect on glycemic control of home-measured A1C versus routine diabetes care.

Design and Methods

This study was a randomized controlled trial in participants with type 2 diabetes stratified by baseline A1C ranging from 7.0 to 8.9% or from 9.0 to 12.9% and randomized to either an intervention group or a control group. The study took place at the adult medicine department at the South End Community Health Center, a federally funded community health center affiliated with Boston Medical Center (BMC), and the Joslin Diabetes Center (JDC), a specialized center for diabetes care. Both sites are located in Boston, MA. The protocol received approval from the JDC and BMC institutional review boards. Study participants gave informed consent in English or Spanish, according to their preference.

Participants

Participants were recruited between June 2010 and February 2012. Patients were eligible if they were between the ages of 20 and 75 years, had physician-diagnosed type 2 diabetes, had a baseline A1C between 7.0 and 12.9% (as measured by study personnel using the

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POC Bayer A1C Now SELF CHECK [A1C Now]), were established patients at one of the clinics, were fluent in English or Spanish, and had a functioning phone for contact during the study. We excluded patients with diabetes-related chronic complications, concomitant chronic illnesses, or physical limitations that would affect their participation in the study; participants with anemia or any condition that could affect red blood cell turnover; and those with type 1 diabetes or gestational diabetes. Initially, only participants with an A1C >7.5% who self-identified as Latino or Hispanic were included in this study. To improve recruitment, the A1C criterion was amended on 8 September 2010 to include participants with an A1C >7.0%, and the ethnicity criterion was amended on 14 January 2011 to include participants of all races and ethnicities. These amendments were approved by both institutional review boards.

Protocol

During a 6-month period, participants in both groups attended three medical visits that occurred in parallel to three study visits; these medical visits were part of their standard diabetes care and took place at baseline, 3 months, and 6 months. The visits included interviews, laboratory testing, and physical examinations. A1C values were obtained at each study visit using two different methods: a laboratory test (A1C Lab) and the POC device (A1C Now). Clinicians were not made aware of A1C Now results at baseline or during subsequent study visits; only A1C Lab values were available during clinic visits.

At baseline, all participants received an informational booklet reviewing basic aspects of type 2 diabetes management and the importance of knowing one's A1C value. This booklet was available in English and Spanish and was developed by the Latino Diabetes Initiative at JDC for use in this study.

Participants were randomized to the control or intervention groups using block randomization. All participants received $15 USD on completion of each study visit and received transportation assistance when needed to attend study-related visits. All participants had full access to the clinical and study staff throughout the study and had timely access to their A1C Lab results taken during routine medical care in a timely manner. The A1C Now results were available to patients at home, and they shared them with the provider on the phone.

Control Group

Participants were reminded about their medical visits as recommended by their clinical team but were not encouraged to participate or dissuaded from participating in any other activities.

Intervention Group

Participants were instructed on the necessary skills and provided the necessary equipment to measure their A1C using the A1C Now device at home at months 1, 2, 4, and 5 of the intervention. They had access to the A1C Now values only during their at-home measurements. Additionally, they were required to have a phone conversation with a nurse practitioner (NP) from their corresponding center as soon as possible after each measurement. The study coordinator scheduled the calls. During each call, the NP asked patients for their A1C Now result and could modify patients' treatment plans (including medications, meal plan, and physical activity) accordingly. Calls were 10–20 minutes in length. Participants were also reminded about their medical visits as recommended by their clinical team.

Outcomes Assessment

The primary outcome variable was change in A1C value as measured with Roche Diagnostics COBAS INTEGRA 800 Plus or COBAS INTEGRA 400 Plus in the central laboratory. Secondary outcomes included blood pressure and BMI. Systolic and diastolic blood pressure measurements were taken with manual sphygmomanometers. Height and weight were collected to measure BMI, which was calculated by dividing weight in kilograms by height in meters squared.

The following characteristics were assessed at baseline: demographic information (age, sex, race/ethnicity, place of birth, language spoken, marital status, number of people in household, education level, income level, and insurance status), diabetes history (years with diabetes and history of diabetes education), and health literacy measured by the Newest Vital Sign (NVS) instrument (5). Each study visit assessed patients' diabetes treatment plan, adherence to medications using the Morisky Medication Adherence Scale (MMAS) (6), and changes in self-care behaviors measured by the Self-Care Inventory–Revised (SCI-R) (7). Diabetes-related emotional distress was evaluated using the Problem Areas in Diabetes (PAID) scale (8) at baseline and 6 months. All questionnaires were administered by an interviewer in English or Spanish, and responses were recorded on paper questionnaires.

Information collected during telephone communications in the intervention group included A1C Now values, meal and exercise plan, and diabetes treatment regimens.

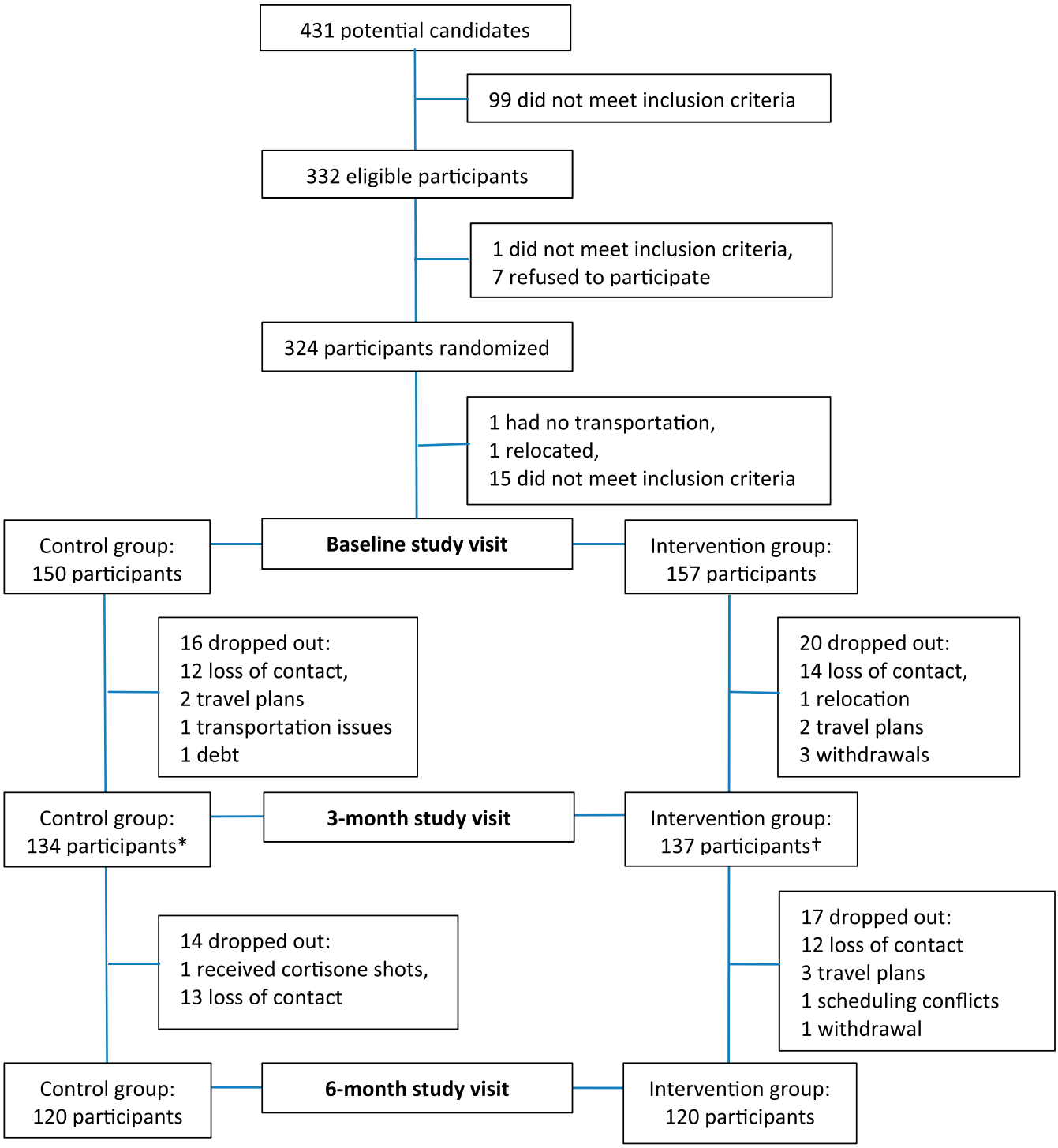

FIGURE 1 Participant flow diagram. *17 participants did not attend visit 2. †16 participants did not attend visit 2.

Notes detailing A1C Now values and treatment modifications that resulted from the calls, if any, were recorded in the clinic's electronic medical record (EMR) system. A1C Lab value and medications were retrieved from the clinic's EMR. At study completion, data were copied from paper questionnaires into the Research Electronic Data Capture (REDCap) data management system (9).

Statistical Analysis

Randomization was performed by using the Random Allocation Program, v. 1.0.0. (Microsoft, Redmond, WA). Randomization criteria included intervention and control groups, as well as stratification by a baseline A1C Now value of 7.0–8.9% or 9.0–12.9%.

TABLE 1 Baseline Characteristics

	Total (n = 307)	Control Group (n = 150)	Intervention Group (n = 157)
Age, years	55.2 (11.4)	56.4 (10.8)	54.1 (11.9)
Female	55.1	57.3	52.9
Race/ethnicity			
Latino	87.6	91.3*	84.1*
Non-Hispanic white	8.8	5.3	12.1
Non-Hispanic black	3.6	3.3	3.8
Married	40.5	36.7	44.2
Live alone	27.4	33.6*	21.8*
Understand English, not born in United States	43.1	44.7	41.5
Education completed, years	10.2 (4.3)	10.1 (4.1)	10.3 (4.4)
Below poverty level	60.8	62.9	58.8
Health insurance			
Government	63.4	66*	60.9*
Private	22.6	25.3*	19.9*
None (self-paid)	14.1	8.7*	19.2*
Reduced health literacy (NVS score <4)	88.0	90.4	85.7
Received diabetes education in the past	67.1	64.4	69.7
Diabetes duration, years	12.0 (10.3)	13.0 (11.9)	11.0 (8.5)
Blood pressure, mmHg			
Systolic	134.9 (19.6)	136.5 (19.0)	133.4 (20.0)
Diastolic	78.6 (8.8)	78.9 (9.2)	78.4 (8.5)
BMI, kg/m^2	32.9 (6.8)	32.7 (5.8)	33.0 (7.7)
A1C Lab, %	8.5 (1.5)	8.5 (1.4)	8.6 (1.6)
A1C Now, %	9.1 (1.6)	9.0 (1.6)	9.2 (1.7)
Participate in physical activity	56.7	57.1	56.4
Exercise, hours/week	3.8 (3.5)	3.8 (3.6)	3.8 (3.5)
SCI-R score (maximum value = 85)	55.2 (11.6)	55.2 (11.8)	55.3 (11.4)
PAID score (maximum value = 100)	25.6 (24.4)	26.8 (23.4)	24.8 (25.3)
MMAS score (maximum value = 8)	6.1 (1.8)	6.0 (2.0)	6.2 (1.7)
Taking oral medications	43.3	44.6	42.0
Using insulin	52.3	50.3	54.1

Data are % or mean (SD). *P <0.05.

Outcome variables were compared within the control and intervention groups separately. Continuous variables were analyzed using linear mixed model with AR(1) covariance structure. Differences between visit 1 and visit 3 were evaluated by defining contrast within the mixed model. To evaluate the effect of the intervention, we included the intervention variable and its interaction with visits in the model. Categorical outcome variables were analyzed similarly using a generalized linear mixed model (i.e., the GLIMMIX procedure in SAS statistical software, 9.4 [SAS Institute, Cary, NC]), and the difference was expressed as odds ratios (ORs). The same analytic approach was taken after stratifying data based on A1C Now at the baseline, as well as with a completers dataset. To examine the effects of important variables on A1C, we first used stratum-specific univariate analysis through which the associations of individual variables with A1C were evaluated. Variables with significant associations at baseline were used in multivariate analysis.

TABLE 2 Intention-to-Treat Analysis

	Control Group				Intervention Group			
	Visit 1 (n = 150)	Visit 2 (n = 108)	Visit 3 (n = 116)	OR (95% CI)	Visit 1 (n = 157)	Visit 2 (n = 117)	Visit 3 (n = 107)	OR (95% CI)
A1C, %	8.5 (0.1)	8.1 (0.1)	8.2 (0.1)*	NA	8.6 (0.1)	8.3 (0.1)	8.1 (0.1)†	NA
BMI, kg/m^2	32.7 (0.6)	32.3 (0.6)	32.6 (0.6)	NA	33.0 (0.5)	32.9 (0.5)	33.1 (0.6)	NA
Blood pressure, mmHg								
Systolic	136.4 (1.6)	134.7 (1.8)	132.2 (1.7)*	NA	133.4 (1.5)	130.8 (1.7)	130.3 (1.7)	NA
Diastolic	79.0 (0.7)	78.6 (0.8)	77.7 (0.8)	NA	78.3 (0.7)	76.6 (0.8)	76.2 (0.8)*	NA
PAID score	26.6 (2.0)	–	18.9 (2.1)†	NA	24.9 (1.9)	–	20.0 (2.0)*	NA
MMAS score	6.0 (0.2)	6.1 (0.2)	6.2 (0.2)	NA	6.1 (0.1)	6.3 (0.2)	6.3 (0.2)	NA
SCI-R score	55.0 (1.0)	55.9 (1.1)	57.9 (1.1)†	NA	55.3 (1.0)	58.5 (1.1)	59.2 (1.1)†	NA
Participate in physical activity, %	57.1 (0.04)	62.6 (0.05)	60.8 (0.04)	1.2 (0.7–1.9)	56.4 (0.04)	71.7 (0.04)	72.5 (0.04)	2.0 (1.2–3.3)*
Exercise, hours/week	3.7 (0.3)	3.3 (0.4)	3.3 (0.3)	NA	3.9 (0.3)	3.7 (0.3)	3.3 (0.3)	NA
Using insulin, %	50.3 (0.04)	52.6 (0.05)	54.6 (0.05)	1.2 (0.7–1.9)	54.1 (0.04)	57.5 (0.05)	57.5 (0.05)	1.1 (0.7–1.8)
Treatment regimen, %								
Lifestyle modification	6.7 (0.02)	3.4 (0.02)	4.2 (0.02)	0.6 (0.2–1.8)	3.8 (0.02)	3.3 (0.02)	5.0 (0.02)	1.3 (0.4–4.1)
Oral medications	44.6 (0.04)	45.3 (0.05)	41.2 (0.05)	0.9 (0.5–1.5)	42.0 (0.04)	40.7 (0.05)	38.6 (0.05)	0.9 (0.5–1.5)

Data from each visit are mean (SE). *P <0.05 compared to baseline. †P <0.001 compared to baseline. NA, not applicable.

Results

Of 431 patients screened, 99 did not meet inclusion criteria (most commonly because they had an A1C <7 or >12.9%, were >75 years of age, or had a chronic complication or concomitant condition). Of the remaining 332, 8 did not meet the inclusion criteria. Of the 324 patients randomized, 1 was excluded because of a lack of transportation, 1 because of relocation, and 15 for not meeting inclusion criteria (Figure 1). Loss to follow-up was not statistically different between groups.

The study included 307 participants with type 2 diabetes (Table 1). The mean age of participants was 55 years, 55% were female, and 40.5% were married. The majority (87.6%) were of Latino origin, of which 85% were born outside of the United States, and 43.1% of those were fluent in English. On average, participants attended school for 10.2 years, 60.8% had an income below the federal poverty level, and 86% had health insurance. On average, participants had had diabetes for 12 years, and the mean baseline A1C was 8.5%. Only 12% of participants had an adequate level of health literacy, defined by a score of 4–6, and 67% had received previous diabetes education.

The two groups had similar baseline characteristics with the exception of ethnicity, number of participants living alone, and insurance status. The control group had more participants who were of Latino ethnicity (91 vs. 84%, P = 0.05), lived alone (33.6 vs. 21.8%, P = 0.02), and had insurance and fewer participants who self-paid for health care (P = 0.03) (Table 1). There was no difference in baseline A1C between groups (8.5 vs. 8.6%, P = 0.2).

At 6 months, all study participants experienced a statistically significant reduction in A1C (control group 0.3%, P = 0.04; intervention group 0.5%, P = 0.0002) (Table 2). There was a statistically significant difference favoring the intervention in the number of people who achieved a reduction of ≥0.5% by 6 months (33.6 vs. 46.7%, P = 0.05). There was no difference between groups in the percentage of participants who attained an A1C <7% (25%).

Anthropometric measurements remained unchanged in both groups. At baseline, 56.7% of all participants reported exercising, and responses did not differ between groups. However, after the intervention, only the intervention group showed a significant increase in the percentage of participants who exercised

TABLE 3 Subgroup Analysis Based on A1C

	Control Group				Intervention Group			
	Visit 1	Visit 2	Visit 3	OR (CI)	Visit 1	Visit 2	Visit 3	OR (CI)
Subgroup with baseline A1C <9%								
	n = 103	*n* = 70	*n* = 76		*n* = 97	*n* = 69	*n* = 64	
A1C, %	7.6 (0.1)	7.6 (0.1)	7.7 (0.1)	NA	7.5 (0.1)	7.5 (0.1)	7.5 (0.1)	NA
BMI, kg/m^2	32.5 (0.6)	31.9 (0.6)	32.5 (0.6)	NA	33.0 (0.6)	32.9 (0.6)	33.0 (0.6)	NA
Blood pressure, mmHg								
Systolic	136.9 (1.9)	137.2 (2.1)	133.0 (2.1)	NA	131.3 (1.9)	130.7 (2.1)	128.6 (2.2)	NA
Diastolic	79.0 (0.9)	78.8 (1.0)	77.8 (1.0)	NA	77.3 (0.9)	76.3 (1.0)	75.0 (1.1)*	NA
PAID score	26.1 (2.3)	–	18.9 (2.5)**	NA	20.5 (2.3)	–	16.1 (2.5)*	NA
MMAS score	6.1 (0.2)	6.3 (0.2)	6.2 (0.2)	NA	6.3 (0.2)	6.4 (0.2)	6.5 (0.2)	NA
SCI-R score	55.5 (1.4)	55.5 (1.4)	57.7 (1.4)*	NA	54.5 (1.4)	58.3 (1.5)	58.3 (1.5)**	NA
Participate in physical activity, %	58.3 (0.05)	67.1 (0.05)	65.0 (0.05)	1.3 (0.7–2.4)	56.3 (0.05)	75.0 (0.05)	77.8 (0.05)	2.7 (1.4–5.4)*
Exercise, hours/week	3.8 (0.4)	3.3 (0.4)	3.4 (0.4)	NA	3.9 (0.4)	3.6 (0.4)	3.2 (0.4)	NA
Using insulin, %	40.8 (0.05)	40.8 (0.06)	44.3 (0.06)	1.2 (0.7–2.2)	42.3 (0.05)	43.1 (0.06)	38.9 (0.06)	0.9 (0.5–1.7)
Treatment regimen, %								
Lifestyle modification	7.8 (0.03)	3.9 (0.02)	5.0 (0.02)	0.6 (0.2–2.1)	6.2 (0.02)	5.5 (0.03)	8.3 (0.03)	1.4 (0.4–4.5)
Oral medications	53.7 (0.05)	54.8 (0.06)	50.7 (0.06)	0.9 (0.5–1.7)	52.2 (0.05)	53.7 (0.06)	56.1 (0.06)	1.2 (0.6–2.3)
Subgroup with baseline A1C ≥9%								
	n = 47	*n* = 38	*n* = 40		*n* = 60	*n* = 48	*n* = 43	
A1C, %	10.3 (0.2)	9.4 (0.2)	9.5 (0.2)*	NA	10.2 (0.2)	9.5 (0.2)	9.2 (0.2)**	NA
BMI, kg/m^2	32.8 (1.1)	32.9 (1.1)	32.8 (1.1)	NA	33.0 (1.0)	33.1 (1.0)	33.3 (1.0)	NA
Blood pressure, mmHg								
Systolic	136.1 (2.8)	130.7 (3.0)	131.7 (3.0)	NA	136.3 (2.5)	130.3 (2.7)	132.3 (2.7)	NA
Diastolic	78.7 (1.3)	77.9 (1.4)	77.1 (1.4)	NA	80.3 (1.1)	77.3 (1.3)	78.4 (1.3)	NA
PAID score	27.8 (3.8)	–	18.9 (4.0)*	NA	32.0 (3.3)	–	26.0 (3.4)*	NA
MMAS, scale	5.8 (0.3)	5.8 (0.3)	6.1 (0.3)	NA	6.0 (0.2)	6.1 (0.3)	6.1 (0.3)	NA
SCI-R score	53.9 (1.6)	56.4 (1.7)	58.1 (1.7)*	NA	56.8 (1.4)	59.2 (1.5)	61.0 (1.5)*	NA
Participate in physical activity, %	54.4 (0.07)	53.9 (0.08)	52.5 (0.08)	0.9 (0.4–2.1)	56.7 (0.06)	66.7 (0.07)	64.6 (0.07)	1.4 (0.6–3.1)
Exercise, hours/week	3.3 (0.6)	3.4 (0.6)	3.0 (0.6)	NA	3.9 (0.5)	4.0 (0.5)	3.7 (0.5)	NA
Using insulin, %	71.7 (0.07)	76.3 (0.07)	75.0 (0.07)	1.2 (0.5–3.1)	73.3 (0.06)	79.2 (0.06)	85.4 (0.05)	2.1 (0.8–5.6)
Treatment regimen, %								
Lifestyle modification	4.3 (0.02)	2.6 (0.02)	2.5 (0.02)	0.6 (0.1–6.8)	–	–	–	NA
Oral medications	25.0 (0.07)	24.2 (0.08)	23.1 (0.07)	0.9 (0.3–2.5)	26.7 (0.06)	21.7 (0.06)	14.6 (0.05)	0.5 (0.2–1.3)

Data from each visit are mean (SE). *P <0.05 compared to baseline. **P <0.001 compared to baseline. NA, not applicable.

TABLE 4 Completers Analysis

	Control Group				Intervention Group			
	Visit 1 (n = 91)	Visit 2 (n = 91)	Visit 3 (n = 91)	OR (CI)	Visit 1 (n = 67)	Visit 2 (n = 67)	Visit 3 (n = 67)	OR (CI)
A1C, %	8.6 (0.2)	8.3 (0.2)	8.3 (0.2)	NA	8.6 (0.2)	8.2 (0.2)	8.0 (0.2)***	NA
BMI, kg/m^2	32.5 (0.7)	32.1 (0.7)	32.4 (0.7)	NA	33.7 (0.8)	33.6 (0.8)	34.0 (0.8)	NA
Blood pressure, mmHg								
Systolic	135.7 (2.2)	134.5 (2.2)	132.1 (2.2)	NA	136.2 (2.5)	130.9 (2.5)	129.3 (2.5)*	NA
Diastolic	78.3 (1.0)	77.8 (1.0)	76.8 (1.0)	NA	79.7 (1.1)	76.1 (1.1)	75.2 (1.1)**	NA
PAID score	27.4 (2.5)	–	20.0 (2.5)**	NA	28.1 (2.8)	–	19.8 (2.8)**	NA
MMAS score	6.1 (0.2)	6.3 (0.2)	6.3 (0.2)	NA	6.4 (0.2)	6.5 (0.2)	6.4 (0.2)	NA
SCI-R score	56.1 (1.3)	56.8 (1.3)	59.2 (1.3)*	NA	57.4 (1.5)	60.0 (1.5)	59.7 (1.5)*	NA
Participate in physical activity, %	57.8 (0.05)	62.6 (0.05)	57.1 (0.05)	1.0 (0.6–1.8)	61.2 (0.06)	70.2 (0.06)	65.7 (0.06)	1.2 (0.4–1.6)
Exercise, hours/week	3.5 (0.4)	3.2 (0.4)	3.2 (0.4)	NA	4.1 (0.4)	3.7 (0.4)	3.0 (0.4)*	NA
Using insulin, %	57.8 (0.05)	58.9 (0.05)	61.1 (0.05)	0.9 (0.6–2.0)	55.2 (0.06)	59.1 (0.06)	56.7 (0.06)	1.1 (0.5–1.8)
Treatment regimen, %								
Lifestyle modification	4.4 (0.02)	3.3 (0.02)	1.1 (0.01)	4.1 (0.02–1.8)	4.5 (0.03)	4.5 (0.03)	4.5 (0.03)	1.0 (0.2–5.1)
Oral medications	37.2 (0.05)	38.1 (0.05)	36 (0.05)	1.1 (0.5–1.7)	39.1 (0.06)	37.7 (0.06)	39.1 (0.06)	1.0 (0.5–2.0)

Data from each visit are mean (SE). *P <0.05 compared to baseline. **P <0.001 compared to baseline. ***P <0.0001 compared to baseline. NA, not applicable.

(from 56.4 to 72.5%, OR 2.0, P = 0.007). On the other hand, there was a nonsignificant decrease in time spent on physical activity in both groups compared with baseline.

In both groups, perception of adherence to diabetes self-care practices increased significantly, and diabetes-related distress decreased significantly. There were no differences in medication use in either group.

As defined a priori, the data were analyzed by strata according to initial A1C. In both groups, A1C was unchanged in participants with a baseline A1C <9%. Participants with a baseline A1C ≥9% had a decrease regardless of group assignment. The control group reduced A1C by 0.8% (P = 0.001), and the intervention group by 1% (P ≤0.0001) (Table 3). There was no between-groups difference in the number of participants who achieved an A1C reduction of ≥0.5% or an A1C <7% regardless of initial A1C. Intervention group participants with a baseline A1C ≥9% were twice as likely to be on insulin at the end of the study as those in the control group, but this difference did not reach statistical significance. Results were otherwise similar to those prior to stratification.

To fully understand the impact of the intervention, a completers analysis was performed. The 67 participants in the intervention group who completed all study visits and the four monthly calls on average reduced their A1C from 8.6 to 8.0% (P <0.0001) (Table 4). In contrast, the decrease in the control group (91 participants) was not significant. The between-groups difference in the percentage of patients who achieved an A1C reduction ≥0.5% was also significant (35.2 vs. 53.2%, P = 0.03) favoring the intervention. There was no difference in those who achieved an A1C <7%. The reduction in blood pressure at 6 months was statistically significant in the intervention group (systolic from 136.2 to 129.3 mmHg, P = 0.008; diastolic from 79.7 to 75.2 mmHg, P = 0.0004). Other variables showed patterns similar to those found in the intention-to-treat analysis.

Correlations were calculated to measure the strength of the relationship between the A1C Now and A1C Lab values. The Pearson correlation coefficient was 0.83, and

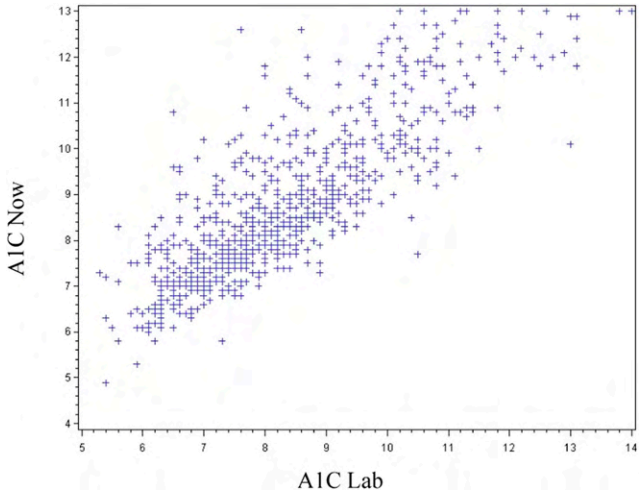

FIGURE 2 Correlation between device- and laboratory-measured A1C values.

the intraclass correlation coefficient was 0.80 (Figure 2 and Table 5).

Discussion

The purpose of this study was to determine whether monthly A1C testing at home by patients with follow-up phone conversations with an NP would lead to significant improvement in glycemic control compared with standard care consisting of periodic office visits. Although reductions in A1C were similar between the intervention and control groups, a higher proportion of subjects in the intervention group achieved a reduction in A1C ≥0.5% at 6 months.

It is not possible to determine the specific weight that each of the two elements of the intervention (A1C testing at home and follow-up call with the NP) had in improving glycemic control. We believe both components are important and complementary. In a quality improvement study, telephone follow-up calls did not show a statistically significant improvement in overall A1C (10). Adherence to the study protocol was difficult because of socioeconomic challenges in the patient population and discrepancies in observed A1C results by participants in the intervention arm. However, participants who completed the full intervention protocol showed a greater reduction in A1C. Participants who started with an A1C ≥9% achieved the largest reduction in A1C in both groups.

Our results are in agreement with those of previous studies in which the availability of current A1C results improved glycemic control (4,11,12). Telephone interventions conducted by nurses and health educators have demonstrated modest improvements in A1C (13,14). Notably, our study demonstrated a significant decline in the A1C values of participants who received calls.

To our knowledge, there are no prior studies examining the effect of home monitoring of A1C on diabetes outcomes. This lack of research highlights the innovative nature of this study and the need to identify actionable information for participants and providers to advance diabetes therapy.

With regard to the advancement in diabetes medications, our study did not find significant differences; more than half of the participants were on insulin before the study, and no significant between-groups differences were found for treatment changes or medication adherence. Previous research suggests that the added benefit of having a current A1C available may be modest when intensification of therapy is already aggressive (11,15). More than 70% of the participants with an A1C ≥9% were already on insulin before the study. Follow-up research could include a similar intervention in participants at earlier stages of diabetes, for whom there may be greater opportunity to escalate therapy.

In our study, both groups showed improvements in self-care behaviors, and significantly more participants in the intervention group engaged in physical activity as a result of the intervention. This result was also observed by Whittemore et al. (13) with a nurse coaching telephone intervention for women with type 2 diabetes.

Our intervention failed to improve adherence to medications, a finding that is consistent with other studies

TABLE 5 Correlation Between Device- and Laboratory-Measured A1C Values

A1C Now Value, %	A1C Lab Value, %
5	5.42
6	6.197
7	6.971
8	7.745
9	8.519
10	9.293
11	10.067
12	10.841

using self-reported questionnaires instead of more reliable measures such as a medication possession ratio, thus identifying an area for further study.

In general, both groups showed improvement in diabetes self-care behaviors, diabetes-related emotional distress, and diabetes control. These results demonstrate that participants in both groups received adequate diabetes education.

Previous studies have shown that POC A1C testing can reduce labor costs and clinic visits (16,17); however, these factors were not tested in our study. Limitations of the study include the discrepancy observed between the A1C Lab and A1C Now values. In more than one-third of cases, the discrepancy was >0.5%, which caused confusion and prevented NPs from advancing therapy. Wide variability has been described in this and similar devices (18). Improved technologies, including newer and more widely available continuous glucose monitoring systems that can be used to calculate A1C, have potential for yielding better outcomes. Also, although we set out to carry out this intervention in the Latino population, difficulties with recruitment led to the decision to include a more diverse population, thus limiting our analysis of any particular racial or ethnic group. There was also a possible risk of selection bias given the loss of subjects from screening to randomization. However, most clinical trials are selective in their inclusion criteria to facilitate higher retention.

Conclusion

This study showed that an intervention using patient-measured A1C in combination with a health care provider–initiated telephone conversation to discuss results and adjust the treatment plan between office visits improved diabetes control in a predominantly minority population. Access to and ease of A1C testing by both patients and providers allow for the use of a shared indicator. Readily available and actionable data, along with more frequent contact, may enhance interactions between patients and providers, allowing them to work as a team with a common goal of lowering A1C.

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DUALITY OF INTEREST

No potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

A.M.-F. designed the study, participated in data analysis, and wrote the manuscript. G.G.-D. participated in data analysis and reviewed/edited the manuscript. S.G. performed the statistical analysis. J.M. reviewed/edited the manuscript. A.E.C. designed and directed the study and reviewed/edited the manuscript. A.M.-F. is the guarantor of this work, had full access to all the study data, and takes responsibility for its integrity and the accuracy of the data analysis.

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