



Use of a Meter With Color-Range Indicators and a Mobile Diabetes Management App Improved Glycemic Control and Patient Satisfaction in an Underserved Hispanic Population: “Tu Salud”—A Randomized Controlled Partial Cross-Over Clinical Study

Laurence B. Katz,¹ Maria Aparicio,² Hilary Cameron,³ and Frederico Ceppa²

¹LifeScan Global Corporation, Malvern, PA; ²La Comunidad Hispana, Kennett Square, PA; ³LifeScan Scotland, Inverness, Scotland, U.K.

OBJECTIVE | To demonstrate the clinical value of OneTouch (OT) Verio Flex glucose meter used in combination with a Spanish-language version of the OT Reveal mobile application (app) to support diabetes care and improve glycemic control in an underserved Hispanic population with type 2 diabetes.

RESEARCH DESIGN AND METHODS | Test subjects ($n = 81$) used the meter and app for 12 weeks, while a randomized control group ($n = 39$) used their own glucose meters without connection to an app. Thereafter, test subjects continued the same regimen for an additional 12 weeks to determine the durability of effect, and control subjects crossed over to use the new meter and app.

RESULTS | Test subjects experienced a mean reduction in A1C of 1.0% after 12 weeks ($P < 0.001$), a statistically significant greater reduction than in control subjects ($P = 0.045$). The improvement in A1C in test subjects was sustained over the next 12 weeks. Crossed-over subjects also demonstrated significant improvements in A1C ($P < 0.001$). Mean blood glucose was reduced significantly without an increase in hypoglycemia, and results in range increased over 12 weeks of meter and mobile app use. Results were independent of subjects' numeracy skills. Subjects using the new meter and app reacted favorably to the tools and expressed improvements in their diabetes treatment satisfaction based on Diabetes Treatment Satisfaction Questionnaire–Change scores.

CONCLUSION | Use of the OT meter and a Spanish-language version of its diabetes management app in an underserved population helped participants achieve a sustained improvement in glycemic control. The tools were well received by the subjects and may have important utility in other low-numeracy, low-literacy populations.

The advent of mobile smartphones has provided an opportunity to improve diabetes care by enabling patients and health care professionals (HCPs) to exchange information via text or e-mail (1). Systematic reviews have found that mobile health interventions improve diabetes care end points such as A1C and are particularly effective if such interventions connect patients with their HCPs (2).

Despite these advances, the prevalence and incidence of type 2 diabetes, as well as rates of hospital admissions and diabetes-related complications within the Hispanic population in the United States are higher than the national average because

of a variety of cultural and social factors (3–5). Furthermore, there have been few studies examining the benefits of interventions in this population. In the Dulce Digital study, text messaging of education and support for Hispanics in poor glycemic control in the San Diego, CA, area yielded greater improvement in glycemic control compared with usual care (6). Telephonic intervention in Latino and African American patients in the South Bronx area of New York, NY, resulted in improved glycemic control (7). In the iDecide study in the Detroit, MI, area, in which 57% of participants were Latinos, interaction with an interactive e-Health tool and follow-up calls demonstrated improvements in patient-reported outcomes but

Corresponding author: Laurence B. Katz, larrykatz@comcast.com

This article contains supplementary material online at <https://doi.org/10.2337/figshare.16564029>

<https://doi.org/10.2337/ds20-0101>

©2022 by the American Diabetes Association. Readers may use this article as long as the work is properly cited, the use is educational and not for profit, and the work is not altered. More information is available at <https://www.diabetesjournals.org/journals/pages/license>.

not A1C (8). In Latina women in the San Diego, CA, area, a tailored physical activity internet intervention demonstrated significant improvement in the time spent on moderate to vigorous physical activity (9).

Recent advances in Cloud-based and mobile diabetes management applications (apps) have enabled new models of collaborative care between patients and their HCPs (10) and given patients the tools to monitor and reflect on their blood glucose results. We previously reported that using a Web-based version of the diabetes management app OneTouch (OT) Reveal in subjects in the United Kingdom was associated with a 0.4% reduction in A1C after 12 weeks (11). In a subsequent study in similar subjects using a mobile version of the app on their own smartphone, improvements in A1C of 0.78% were observed in patients with type 1 or type 2 diabetes after 12 weeks (12).

There is a great need to generate clinical evidence in people with diabetes in underserved populations where low numeracy, literacy, and diabetes understanding can contribute to poorer glycemic control (13–15). Easy-to-use meters with color-coded glucose range indicators are useful in patients with low numeracy (16). This study sought to demonstrate the clinical value and user acceptance of the Bluetooth-enabled OT Verio Flex meter used in combination with a Spanish-language version of the OT Reveal mobile app to improve overall diabetes care, glycemic control, and patient-reported outcomes in an underserved Hispanic community in southeastern Pennsylvania.

Research Design and Methods

Study Design and Patients

The Tu Salud study was a parallel arm, open-label, randomized, controlled, partial cross-over study in subjects with diabetes in an underserved, predominantly Spanish-speaking population. Its primary objective was to demonstrate improved glycemic control in people with diabetes using the OT Verio Flex glucose meter and the OT Reveal mobile app system (test group) compared with subjects continuing to use their own glucose meter without connection to a mobile diabetes app (control group). Protocol and consent documents were approved by an institutional review board, and all participants provided written, informed consent after receiving a detailed written description of the study in their native language. Subjects were given Spanish-language translations of all written study materials. The study was registered with ClinicalTrials.gov (NCT03556605). The first subject enrolled on 30 July 2018, and the last subject completed the study on 15 September 2019.

Subjects were randomized into test or control groups in a 2:1 ratio. For the first 12 weeks, test subjects used the new meter and mobile app, and control subjects continued to use their own glucose meter without connectivity to a diabetes app. After 12 weeks, control subjects crossed over to the same treatment as the test group for an additional 12 weeks, while original test group subjects continued to use the new meter and app for an additional 12 weeks to test the durability of effects (Figure 1). Training on the meter, app, and smartphone (as needed) were done by the clinic staff.

Blood glucose monitoring (BGM) data were transmitted automatically from meters to smartphones containing the diabetes management app and automatically uploaded via the Cloud to a Web-based version of the app accessible on the HCPs' office computers. HCPs reviewed the 14-day report for each subject and texted a descriptive emoji and brief comments to each patient's smartphone every 2 weeks based on the report (Figure 2). Testing reminders could also be set on the mobile app and sent to the smartphone.

This study recruited patients from La Comunidad Hispana Health Center, a federally qualified health center in southern Chester County, PA, dedicated to serving the needs of a primarily Spanish-speaking Latino population drawn to the area by jobs in the mushroom farming industry. The clinic is staffed by physicians, diabetes educators, and nurses trained in diabetes care.

Inclusion criteria included age 18–70 years, diagnosis with type 1 or type 2 diabetes ≥ 3 months before screening, A1C $\geq 7.5\%$ at baseline, and current BGM at home for diabetes management decisions. Exclusion criteria included pregnancy, current use of the OT Verio Flex glucose meter or OT Reveal mobile app, or current use of a continuous glucose monitoring system or insulin pump. Subjects not having smartphones were provided a used iPhone 6 with limited calling privileges.

Study Procedures

The study was conducted in the following periods.

Visit 1 (Screening/Baseline)

Screening procedures included obtaining informed consent, collecting demographics and medical history information, performing a capillary blood collection for point-of-care (POC) A1C measurement, and evaluating whether subjects met entrance criteria. Randomization of eligible subjects occurred at the same visit as the screening. Participants in the test group were given an OT Verio Flex meter and OT Reveal mobile app and trained in their use.

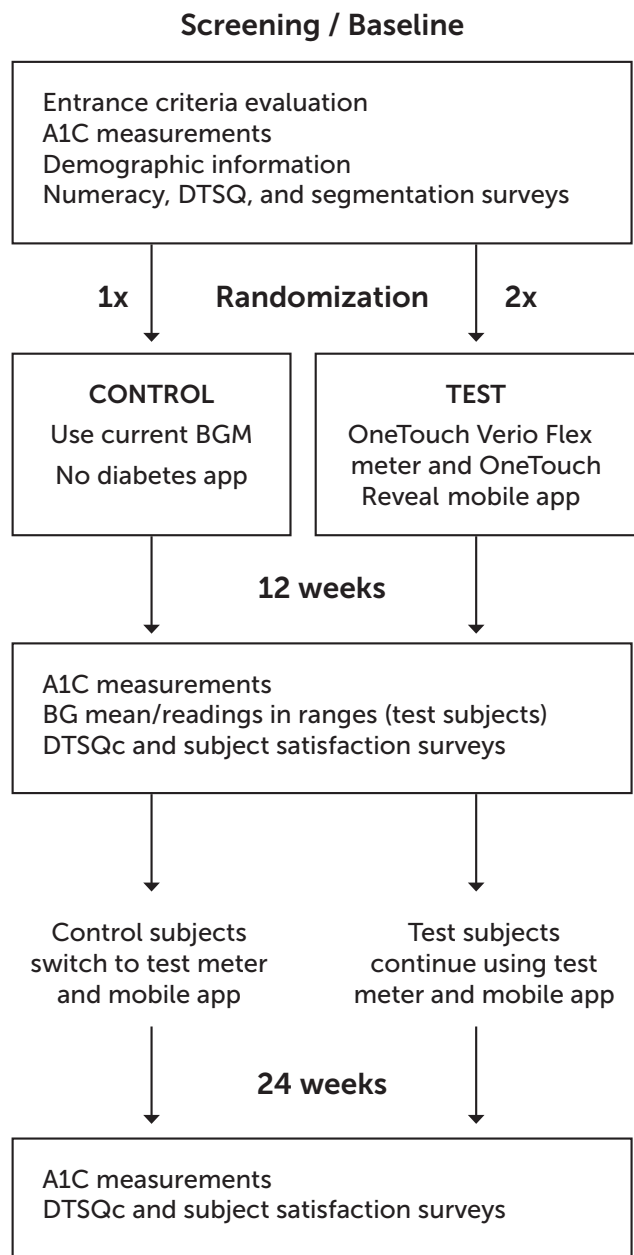


FIGURE 1 Study design. Subjects were randomized in a 2:1 ratio to the test group (using OT Verio Flex meter plus OT Reveal mobile app) or the control group (continuing to use their own blood glucose meter and no app). After 12 weeks, control subjects were switched to the OT meter and app for 12 weeks, and test subjects continued using the OT meter and app until week 24. BG, blood glucose.

All randomized subjects completed a subjective numeracy assessment, the Diabetes Treatment Satisfaction Questionnaire (DTSQ), and a self-segmentation categorization. The numeracy assessment used a validated subjective numeracy scale (17,18), in which subjects read eight statements and chose from six potential responses to each statement that most represented themselves (Supplementary Figure S1). For the DTSQ, subjects

answered eight questions regarding satisfaction with their current diabetes treatment (Supplementary Figure S2). For self-categorization, subjects indicated with which of three statements they most identified (Table 1). Only the statements were shown to the subjects, not the titles, and all statements were translated into Spanish and either read by or read to the subjects.

Visit 2 (Week 12 ± 7 Days)

A capillary collection was performed for POC measurement of A1C. HCPs discussed diabetes management progress with control subjects based on their own meter data and with test subjects based on the 14-day OT Reveal reports. For the DTSQ, all subjects answered questions regarding the change in their satisfaction with their diabetes treatment compared with the last time they answered the questionnaire (Supplementary Figure S3). Test subjects answered a series of statements regarding their satisfaction with the OT meter and mobile app. Finally, HCPs provided and explained the new meter and mobile app to crossed-over control subjects.

Visit 3 (Week 24 ± 7 Days)

A capillary blood collection was performed for POC measurement of A1C. After using the OT meter and app for 12 weeks, crossed-over control subjects answered the same series of statements as did test subjects at visit 2.

Randomization, End Points, and Statistical Analysis

Subjects were randomized using a stratified block randomization design. Stratification into three levels was based on baseline A1C: 7.5 to ≤9.0%, >9.0 to ≤10.5%, and >10.5%. Primary end point analysis calculated individual subject difference in A1C from baseline to 12 weeks for each group. The change from baseline for test subjects compared with control subjects was assessed using covariate adjusted mean differences. The success criterion was test subjects demonstrating a statistically significant greater reduction in A1C at 12 weeks compared with control group subjects using their own meter.

Results

Demographics

A total of 120 subjects were enrolled, of whom 81 were randomized to the test group and 39 to the control group. Baseline demographics for each group and participants as a whole are shown in Table 1. Of the 120 subjects enrolled, approximately half were male. Mean age was 51.1 years with a mean of 3.0 years since diagnosis of diabetes. Mean baseline A1C was 9.6%, and mean BMI was 31.3 kg/m². There was no significant difference between the baseline means in test and control subjects in any of these parameters. Nearly all the subjects



FIGURE 2 Subject data flow. Test (baseline to week 24) and control (week 12 to week 24) subjects used the OT Verio Flex meter to conduct BGM according to the schedule suggested by their HCP. BGM data were transmitted wirelessly from the meter to the smartphone containing the Spanish-language version of the diabetes management mobile app OT Reveal. BGM data were automatically uploaded via the Cloud to a Web-based version of the app accessible to the HCPs on their office computers. HCPs reviewed the 14-day Web-based report for each subject to assist in formulating diabetes-related text messages sent to the subjects' smartphone.

had type 2 diabetes, and 95% were of Hispanic or Latino ethnicity. Nearly all had never used diabetes management software or had their HCP download their blood glucose data from their meter. More than half of the subjects had either no formal education (16%) or only primary school education (50%); 32% had some secondary or technical school training, and only 2% had some college education. More than half of the subjects listed home management (33%); farming, fishing, and forestry (11%); or construction/maintenance (8%) as their occupation. Sixty percent of patients were on oral medication, and the remainder were using mealtime or basal insulin. Seventy of the 120 subjects were provided smartphones. Loading of the app on the phone was done by clinic staff in about 85% of the cases. Synchronizing of blood glucose data were automatic each time the subject opened the app.

Subjective Numeracy Scale Evaluation

Subjective numeracy scores at baseline ranged from 8 to 48, with a mean of 27.1 and a median of 26 (Table 1). The median score of 26 was significantly lower ($P = 0.004$) than those observed previously in our ASPIRE (12) and SPECTRA (19) meter and app studies, in which predominantly White subjects from urban and suburban areas of the United Kingdom had median self-reported numeracy scores of 32 and 34, respectively.

Patient Segmentation Categorization

For patient segmentation categorization, 67% of subjects self-identified their diabetes situation with the statement associated

with being “overwhelmed,” and 16 and 18% self-identified with statements associated with “quick answer” and “managing,” respectively (Table 1). In 2008, the Rosetta Study (G. Hurrell, unpublished observations) examined >4,500 adults with diabetes in the United States, France, Germany, China, Russia, and Japan and found that 32% segmented as “quick answer,” 36% as “managing,” and 32% as “overwhelmed.” This roughly one-third identification in each segment was validated in 2013 in a U.S. study (G. Hurrell, unpublished observations). In two more recent prospective outcome studies involving people with diabetes in the United Kingdom, percentages in the “quick answer,” “managing,” and “overwhelmed” categories were 35, 60, and 5%, respectively (11), and 24, 50, and 26, respectively (12).

Subject Withdrawals and Exclusions From Data Analysis

Of the 120 subjects who started the study, 112 (75 in the test group and 37 in the control group) completed visit 2 for an overall dropout rate of 6.7%. A total of 103 subjects (71 test and 32 control) completed visit 3 (end of study) for a final overall dropout rate of 14.2%. Of the 17 withdrawals, 8 withdrew consent, 8 were lost to follow-up, and 1 became pregnant.

A1C data analysis was conducted with and without two subjects (one from the test group and one from the control group) who had 12-week A1C declines from baseline of 7.1% and 5.9%, respectively, both of which were >3 SDs from the mean (z scores of -3.5 and -5.1 , respectively). It was suspected (although could not be confirmed) that

TABLE 1 Baseline Demographics

	Test (N = 81)	Control (N = 39)	Total (N = 120)
Sex, n (%)			
Male	42 (52)	19 (49)	61 (51)
Female	39 (48)	20 (51)	59 (49)
Age, years, mean (range)	51.6 (24–83)	50.0 (36–68)	51.1 (24–83)
Years since diagnosis, mean (range)	2.9 (0.1–14.1)	3.4 (0.3–12.8)	3.0 (0.1–14.1)
Years performing BGM, mean (range)	2.7 (0.1–10.0)	3.4 (0.3–12.8)	2.9 (0.1–12.8)
BMI, kg/m ² , mean (SD)	31.1 (5.7)	31.6 (6.8)	31.3 (6.1)
A1C, %, mean (SD)	9.63 (1.64)	9.56 (1.50)	9.61 (1.59)
Diabetes type, n (%)			
Type 2 diabetes	81 (100)	37 (95)	118 (98)
Type 1 diabetes	0 (0)	2 (5)	2 (2)
Ethnicity, n (%)			
Hispanic or Latino	77 (95)	37 (95)	114 (95)
Not Hispanic or Latino	4 (5)	2 (5)	6 (5)
Use diabetes management software, n (%)			
Never	80 (99)	39 (100)	119 (99)
Once	1 (1)	0 (0)	1 (1)
HCP downloads BGM data, n (%)			
Never	80 (99)	39 (100)	119 (99)
Missing information	1 (1)	0 (0)	1 (1)
Highest education level, n (%)			
Some college	1 (1)	1 (3)	2 (2)
Technical trade school	3 (4)	1 (3)	4 (3)
Secondary school	26 (32)	9 (23)	35 (29)
Primary school	39 (48)	21 (54)	60 (50)
None	12 (15)	7 (18)	19 (16)
Occupation, n (%)			
Home management	24 (30)	16 (41)	40 (33)
Farming, fishing, forestry	9 (11)	4 (10)	13 (11)
Construction, maintenance	7 (9)	3 (8)	10 (8)
Transportation services	8 (10)	2 (5)	10 (8)
Professional, sales, management	5 (6)	2 (5)	7 (6)
Retired	4 (5)	0 (0)	4 (3)
None (including unemployed)	8 (10)	1 (3)	9 (8)
Other	16 (20)	11 (28)	27 (23)
Numeracy score, n (%)*			
1–8	3 (4)	2 (5)	5 (4)
9–16	9 (11)	2 (5)	11 (9)
17–24	24 (30)	10 (27)	34 (29)
25–32	18 (23)	10 (27)	28 (24)
33–40	16 (20)	11 (30)	27 (23)
41–48	9 (11)	2 (5)	11 (9)
Numeracy score, median, mean (SD)*	26, 27.1 (10.2)	29, 27.2 (9.9)	26, 27.1 (10.0)
Patient segmentation category, n (%)†			
Quick answer	12 (15)	7 (18)	19 (16)
Managing	10 (12)	11 (28)	21 (18)
Overwhelmed	59 (73)	21 (54)	80 (67)

*Data based on available numeracy scores for 79 test subjects and 37 control subjects (116 total participants). †Subjects indicated with which of the following three statements they most identify. Only the statements were shown to the subjects—not the titles. All statements were translated into Spanish and either read by or read to the subjects. Quick answer: Most of the time I am managing my diabetes well. I test my blood glucose levels and take my medicines as the doctor recommends and am happy to just get on with my life. Managing: Most of the time I am managing my diabetes well. I test my blood glucose levels and take my medicines as the doctor recommends, and I am always on the lookout for new ways to improve my diabetes care even more. Overwhelmed: Most of the time it is hard managing my diabetes. It is hard to do all the things you need to do to take care of it, and I could do with more help, especially with keeping to a healthy diet.

errors in POC A1C testing had occurred. Data analysis with and without these two outliers did not lead to different conclusions. Analysis of all other parameters included all subjects who finished visits 2 and 3 and had data available.

Changes in A1C

Mean A1C at baseline was 9.57% in test subjects ($n = 80$) and 9.47% in control subjects ($n = 38$) (Table 2), excluding two subjects based on the rationale described above. Although no statistical difference existed between mean baseline A1C values ($P > 0.05$), covariate analysis, which takes into account numerically different A1C starting points, was used for A1C analysis at week 12 and week 24.

Mean A1C in 74 evaluable test group subjects at 12 weeks was 8.48% (Table 2). The individual paired mean reduction in A1C compared with baseline of -0.99% was highly significant ($P < 0.001$). The improvement in A1C was sustained over the subsequent 12 weeks, and although there was a small additional improvement in individual paired A1C values at week 24 (-0.16%), this difference was not statistically significant ($P > 0.05$).

Mean A1C in 36 evaluable control group subjects was 8.82% at 12 weeks (Table 2). This reduction was statistically significant compared with baseline ($P < 0.01$), and the 0.36% greater reduction in paired mean A1C values in the test group versus the control group at week 12 (primary end point) was also statistically significant ($P = 0.045$). After control subjects were switched at week 12 to the OT meter and app, there was a further highly significant improvement in A1C of -0.55% ($P < 0.001$) in the next 12 weeks (Table 2).

Subgroup analysis was conducted comparing A1C changes in test and control subjects based on whether subjects fell above or below the median group numeracy score. In both groups, reduction in A1C was the same whether numeracy skills were above or below the median numeracy score of 26. This finding implies that the features of the meter and app were equally efficacious in subjects with low and high numeracy skills.

Blood Glucose Values

Blood glucose results from the first 2 weeks of new meter and app usage in test subjects were compared with weeks 10–12 in 63 available subjects. Baseline mean blood glucose of 199.0 mg/dL was reduced by 8.1% after using the OT meter and app ($P = 0.02$). The percentage of in-range blood glucose results (70–180 mg/dL) increased by 10.4% from 47.7 to 58.1% and above-range glucose results (>180 mg/dL) declined 10.8% from 51.2 to 40.4%. The frequency of below-range glucose results (<70 mg/dL) remained unchanged at $<1.5\%$ overall, indicating no increase in hypoglycemic events.

Subject Acceptance Survey

Test group subjects ($n = 74$) and crossed-over control subjects ($n = 30$) answered subject acceptance survey questions after 12 weeks of using the new meter and app. Supplementary Table S1 shows the results of the survey combining the responses of both groups. All favorable “meter,” “meter and mobile app,” and “testing reminder on your cell phone” responses were statistically significant (i.e., lower 95% CI limit $>50\%$). None of the “pattern feature on the mobile app” favorable responses

TABLE 2 Changes in A1C

	Test*		Control†	
	<i>n</i>	Mean ± SE	<i>n</i>	Mean ± SE
A1C				
Baseline	80	9.57 ± 0.18	38	9.47 ± 0.23
Week 12	74	8.48 ± 0.15	36	8.82 ± 0.22
Week 24	70	8.31 ± 0.16	31	8.16 ± 0.20
Change in A1C‡				
Weeks 0–12	74	−0.99 ± 0.14§	36	−0.63 ± 0.20
Weeks 12–24	70	−0.16 ± 0.13¶	31	−0.55 ± 0.13§
Test versus control subjects at week 12	110	−0.36 ± 0.21#		

Data analysis shown is without subjects LCH039 (test group) and LCH108 (control group) based on rationale described in text. *Test subjects used OT Verio Flex meter and OT Reveal mobile app for 24 weeks. †Control subjects used their own meter and no mobile app for the first 12 weeks and switched to the OT meter and app for the next 12 weeks. ‡Mean of paired changes from baseline to week 12 and from week 12 to week 24 in each individual subject. Difference in means may not equal the mean of paired changes because paired changes were calculated using the differences in each individual subject and only for those subjects having A1C values for baseline and week 12 or week 24. §Significant within-group change ($P < 0.001$). ||Significant within-group change ($P < 0.01$). ¶Within-group change not significant ($P > 0.05$). #Significant reduction in A1C in test group compared with control group ($P = 0.045$; one-tailed test).

were statistically significant because of the high number of neutral responses.

DTSQ Change Scores

After 12 weeks, test group subjects indicated significantly improved diabetes treatment satisfaction ($P < 0.05$) compared with the satisfaction level expressed by control group subjects on five of the eight DTSQ Change (DTSQc) questions (Supplementary Table S2). At 24 weeks, test group subjects continued to show improvement in their diabetes treatment satisfaction in six areas compared with week 12. At 24 weeks, control group subjects who had been switched to the OT meter and app also expressed a significantly greater degree of satisfaction than at their week 12 baseline in six of the eight questions.

HCP Advice via Text Messaging

Text messages were divided for ease of analysis into five categories: 1) diet, food, lifestyle, and exercise; 2) BGM regimen; 3) insulin adjustment; 4) oral medication/glucagon-like peptide 1 receptor agonist adjustment; and 5) diabetes on track. Test subjects ($n = 76$) received a total of 780 messages during the 24 weeks of the study. Crossed-over control subjects ($n = 37$) who used the new meter and app between weeks 12 and 24 received a total of 175 messages. Multiple messages could be sent to the same subject over the course of the study.

By far, the most frequent message was “diabetes on track.” Ninety-eight percent of all subjects received that message at least once during the study (Supplementary Table S3). Nearly 39% of subjects received a message related to diet, food, lifestyle, and exercise, and >28% received a message related to their BGM regimen at least once during the study. Almost 17% of subjects received at least one message related to insulin adjustment, and almost 10% received at least one message related to other medication adjustments.

Messages also included accompanying emojis because many of the subjects possessed low reading skills. Examples of some of these emojis are shown in Supplementary Figure S4.

Safety

In the 114 subjects for whom adverse events were collected, 61 adverse events were reported in 48 different subjects (42.1%) during the study. Most adverse events were mild or moderate and not related to diabetes. There was one serious adverse event (SAE) reported by the site; a subject was hospitalized for toe amputation due to infection. The SAE was considered to be unrelated to the study. One subject was brought to the emergency room and released with a diagnosis of Bell's palsy,

but the incident was considered an adverse event rather than an SAE by the investigator.

Discussion

This study sought to demonstrate the clinical value and user acceptance of the Bluetooth-enabled OneTouch Verio Flex blood glucose meter used in combination with a Spanish-language version of the OneTouch Reveal mobile app to improve overall diabetes care, glycemic control, and patient satisfaction in people with diabetes in an underserved, low-numeracy, low-literacy, Hispanic population. More than half of the subjects had only primary school or no formal education. Subjects expressed a low subjective numeracy evaluation and segmented themselves as “overwhelmed” in much higher numbers than subjects in other studies. Because newly diagnosed patients can often feel overwhelmed by their diabetes diagnosis, it is important to emphasize that nearly all patients in this study had longstanding diabetes; thus, their feeling of being overwhelmed was not the result of a recent diagnosis, but rather reflected their general feeling of lack of control over their diabetes.

Subjects randomized to the test group had a highly significant mean reduction in A1C of $\sim 1.0\%$ after 12 weeks. Again, it is important to note that nearly all subjects had established diabetes for >1 year because newly diagnosed patients tend to adhere better to treatment instructions and directions and often will have greater A1C reductions. The improvement in A1C was sustained over the next 12 weeks. We recognize that it would have been valuable to observe these subjects for an additional 6–12 months to see if the improvement in A1C was maintained; however, that was not possible.

Subjects randomized to the control group also demonstrated an A1C reduction, although it was less statistically significant than in the test group. The A1C reduction in the control group was greater than anticipated considering that no study-related intervention or communication occurred as part of the study protocol. However, these subjects were aware that they were in a clinical trial, and this placebo, or Hawthorne, effect (20) may have contributed to the reduction in A1C. Potentially adding to this effect was the strong desire of these subjects to be viewed favorably by their HCPs. Also, even though there was no protocol-directed interaction between control subjects and HCPs during the first 12 weeks of the study, subjects could still come to the clinic if health issues arose, which could have contributed to A1C improvement in the control group if diabetes management was addressed during these visits. Finally, control subjects were aware that they would receive the OT meter and app after 12 weeks. Perhaps in a desire to please the investigators and thus to be

considered eligible to receive the new meter and mobile app (and study-supplied cell phone), they may have paid closer attention to diabetes management instructions from their HCP even though they were told they would receive the new tools regardless of their results after 12 weeks.

In an attempt to give all subjects the opportunity to experience the new meter and app, control subjects were switched to these products at week 12. In retrospect, it might have been advantageous to have only half of the control subjects switch to the new meter and app and the remainder to continue as control subjects to see if subsequent A1C improvement was the result of this switch. However, that would have reduced the sample size in half and prevented some subjects from getting the new treatment modality. Despite this shortcoming, the A1C improvement after switching to the new modality was significant, especially considering that the reduction started from a much lower A1C than at the start of the study.

We recognize that is difficult to determine whether changes in A1C were the result of medication optimization, improved diabetes education via the diabetes management app, lifestyle changes, increased testing, or increased understanding of blood glucose readings. In the real world, all of these aspects can contribute to improvement in A1C. By conducting a controlled, partial cross-over study, we attempted to tease out the effect of the meter and app. We believe the study demonstrates that the meter and app are important tools that help to enable all of these factors and thereby contribute to A1C improvement.

Mean blood glucose values retrieved from the app improved significantly over the 12 weeks of meter and app use. Results in range and results above range also improved. Importantly, there was no increase in hypoglycemic results despite the decrease in blood glucose overall. Improvements in glucose and A1C were independent of whether subjects expressed low or high subjective numeracy.

Test and control subjects using the new meter and app reacted favorably to multiple statements about both products. Similarly, subjects expressed improvements in their diabetes treatment satisfaction as indicated by DTSQc scores. Anecdotally, HCPs expressed satisfaction with having real-time access to their patients' data and a 14-day summary report via the OT Reveal desktop app.

It is important to understand how the meter and app affect the time spent by HCPs on patient care, as technology can increase, decrease, or have a neutral effect on provider time spent in this way. In this study, HCPs spent time reviewing the website to look at the blood glucose results, but because the website was easy to read and trends were shown graphically,

the HCPs were able to make quick conclusions and decisions. In addition, the HCPs trusted the data from the website more than from patients' hand-written logbooks. The accurate and reliable data made managing patients with diabetes—particularly those on insulin—faster and easier. Some additional time was needed to access the website and find patient's data within it, but because the HCPs were routinely on the computer using electronic medical records, they were able to perform this task very quickly.

Conclusion

Use of OT Verio Flex meter and OT Reveal mobile app in an underserved Hispanic population with predominantly type 2 diabetes, low numeracy, and feelings of being overwhelmed by their diabetes helped to provide a sustained improvement in glycemic control without an increase in hypoglycemic events. The meter and mobile app were well received by the subjects and may have important utility in similar low-numeracy, low-literacy populations.

ACKNOWLEDGMENTS

The authors thank Johana Guzman, study coordinator at La Comunidad Hispana (LCH); Stephanie Lee, clinical research associate at InClinica, Inc.; Dr. David Shearer, safety monitor at LifeScan Global Corporation; and Amparo Gonzalez, LifeScan Global Corporation, for assistance in the conduct of the study. They also thank Maria Weir for translating written study materials into Spanish and Drs. Elizabeth Holt, Brian Levy, and Mike Grady for review of the manuscript.

FUNDING

The study was funded by LifeScan Global Corporation. The contract research organization, InClinica, Inc., was funded by LifeScan Global Corporation. The clinical site, LCH, received no financial compensation other than donation of study supplies.

DUALITY OF INTEREST

L.B.K. and H.C. are employees of LifeScan, Inc., and M.A. and F.C. are employees of LCH. No other potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

L.B.K. designed the study, wrote the protocol and manuscript, and prepared the tables and figures. M.A. and F.C. helped to edit the protocol and conducted the study. H.C. wrote the statistical analysis plan, analyzed the data, and generated result tables. L.B.K. 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.

REFERENCES

1. Steinhubl SR, Muse ED, Topol EJ. Can mobile health technologies transform health care? *JAMA* 2013;310:2395–2396
2. Garabedian LF, Ross-Degnan D, Wharam JF. Mobile phone and smartphone technologies for diabetes care and self-management. *Curr Diab Rep* 2015;15:109
3. Agency for Healthcare Research and Quality. National Healthcare Quality Report, 2013 (AHRQ Publication No. 14-0005).

- Rockville, MD, U.S. Department of Health and Human Services, 2014
4. Testerman J, Chase D. Influences on diabetes self-management education participation in a low-income, Spanish-speaking, Latino population. *Diabetes Spectr* 2018;31:47–57
 5. Aguayo-Mazzucato C, Diaque P, Hernandez S, Rosas S, Kostic A, Caballero AE. Understanding the growing epidemic of type 2 diabetes in the Hispanic population living in the United States. *Diabetes Metab Res Rev* 2019;35:e3097
 6. Fortman AL, Gallo LC, Garcia MI, et al. Dulce Digital: an mHealth SMS-based intervention improves glycemic control in Hispanics with type 2 diabetes. *Diabetes Care* 2017;40:1349–1355
 7. Tabaei BP, Howland RE, Gonzalez JS, et al. Impact of a telephonic intervention to improve diabetes control on health care utilization and cost for adults in South Bronx, New York. *Diabetes Care* 2020;43:743–750
 8. Hoffer R, Hwajung C, Mase R, et al. Mediators and moderators of improvements in medication adherence: secondary analysis of a community health worker-led diabetes medication self-management support program. *Health Educ Behav* 2017;44:285–296
 9. Marcus BH, Hartman SJ, Larsen BA, et al. Pasos Hacia La Salud: a randomized controlled trial of an internet-delivered physical activity intervention for Latinas. *Int J Behav Nutr Phys Act* 2016;13:62
 10. Hsu WC, Lau KHK, Huang R, et al. Utilization of a cloud-based diabetes management program for insulin initiation and titration enables collaborative decision making between healthcare providers and patients. *Diabetes Technol Ther* 2016;18:59–67
 11. Grady M, Cameron H, Levy BL, Katz LB. Remote health consultations supported by a diabetes management Web application with a new glucose meter demonstrates improved glycemic control. *J Diabetes Sci Technol* 2016;10:737–743
 12. Grady M, Katz LB, Cameron H, Levy BL. Diabetes app-related text messages from health care professionals in conjunction with a new wireless glucose meter with a color range indicator improves glycemic control in patients with type 1 and type 2 diabetes: randomized controlled trial. *JMIR Diabetes* 2017;2:e19
 13. Marden S, Thomas PW, Sheppard ZA, Knott J, Lueddeke J, Kerr D. Poor numeracy skills are associated with glycaemic control in type 1 diabetes. *Diabet Med* 2012;29:662–669
 14. Al Sayah F, Majumdar SR, Williams B, Robertson S, Johnson JA. Health literacy and health outcomes in diabetes: a systematic review. *J Gen Intern Med* 2013;28:444–452
 15. Zikmund-Fisher BJ, Exe NL, Witteman HO. Numeracy and literacy independently predict patients' ability to identify out-of-range test results. *J Med Internet Res* 2014;16:e187
 16. Grady M, Katz LB, Cameron H, Levy BL. A comprehensive evaluation of a novel color range indicator in multiple blood glucose meters demonstrates improved glucose range interpretation and awareness in subjects with type 1 and type 2 diabetes. *J Diabetes Sci Technol* 2016;10:1324–1332
 17. Fagerlin A, Zikmund-Fisher BJ, Ubel PA, Jankovic A, Derry HA, Smith DM. Measuring numeracy without a math test: development of the Subjective Numeracy Scale. *Med Decis Making* 2007;27:672–680
 18. Dolan JG, Cherkasky OA, Li Q, Chin N, Veazie PJ. Should health numeracy be assessed objectively or subjectively? *Med Decis Making* 2016;36:868–875
 19. Grady M, Katz LB, Strunk CS, Cameron H, Levy BL. Examining the impact of a novel blood glucose monitor with color range indicator on decision-making in patients with type 1 and type 2 diabetes and its association with patient numeracy level. *JMIR Diabetes* 2017;2:e24
 20. Frank RH, Kaul JD. The Hawthorne experiments: first statistical interpretation. *Am Sociol Rev* 1978;43:623–643