FEATURE ARTICLE

Culturally Congruent Latino-Adapted Telemonitoring of Underrepresented Adults With Type 2 Diabetes: The CULTURA-DM2 Trial

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This study reports on the development and testing of a comprehensive diabetes telemonitoring program tailored to meet the needs of underserved Hispanic/Latino patients with diabetes. Individuals participating in the culturally tailored program had significantly better 6-month outcomes than those receiving comprehensive outpatient management for A1C, blood pressure, and diabetes self-efficacy, with no differences between groups in quality of life, medication adherence, emotional functioning, patient activation, or unscheduled physician visits. These findings suggest that culturally congruent diabetes telemonitoring may be effective for this underserved population.

In the United States, the prevalence of type 2 diabetes in Hispanic/Latino (H/L) adults is almost twice that in non-H/L White adults (1,2). Type 2 diabetes is a leading cause of disability and death (3). The risk of mortality for people with type 2 diabetes is two to three times higher than for those without type 2 diabetes, with a reduced life expectancy of up to 8 years (2). Many H/L people in the United States face multiple barriers that may prevent efficient diabetes management, including negative social determinants of health; 16.9% live in poverty versus 7.8% of non-Hispanic White people, and 9.8% (vs. 7.4%) have household incomes <$15,000/year (4,5). Low English comprehension levels, lack of health insurance, cultural beliefs, low literacy and health literacy levels, low education levels, low socioeconomic status, poor patient-provider matches, and high treatment costs have also been cited as barriers (6–8).

Two systematic reviews have reported that diabetes telehealth management (DTM) significantly improves glucose management; however, <25% of randomized controlled trials (RCTs) have enrolled ethnically diverse patients (9–11). A meta-analysis by Polisena et al. (12) also reported positive glucose management results, noting a need to assess and adapt technology to optimize use among different populations. Another meta-analysis by Marcolino et al. (13) recommended community-based participatory research (CBPR) approaches to enhance persistence in medication usage and treatment adherence. However, few studies have examined digital health technologies in minoritized populations or have specifically tailored them to fit cultural, linguistic, and other needs (14,15).

There is limited evidence of the generalizability of improvements in A1C from DTM in H/L minoritized populations. Several studies have included H/L subjects, but none focused on H/L individuals exclusively (16,17). A 2023 systematic review enrolling Black and H/L patients with diabetes reported overall improvements in A1C (18); another review focusing on H/L patients with type 2 diabetes found that promising interventions

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This article contains supplementary material online at https://doi.org/10.2337/figshare.27018094.

https://doi.org/10.2337/cd24-0002

included making literacy modifications, providing recipes, addressing cultural beliefs, encouraging participation by family and/or friends, seeking community input, and offering experiential learning (19). In addition, telehealth potentially offers an opportunity to improve health care access, particularly in locations where transportation systems are inadequate.

Previous research has not used CBPR approaches involving H/L patients and other stakeholders in tailoring DTM to enhance engagement and treatment adherence (12,13). The IDEATel (Informatics for Diabetes and Education Telemedicine) study found that a type 2 diabetes telemedicine intervention improved cholesterol, A1C, and blood pressure over 5 years in older, medically underserved, ethnically diverse patients (20,21).

While these seminal results remain very encouraging, iterative tailoring based on stakeholder input is imperative. There is currently a high interest in telehealth, promulgated by the coronavirus disease 2019 (COVID-19) pandemic, as well as widespread adoption, with >85% of the world's population having access to mobile phones (22). H/L communities use the Internet from their mobile phones at rates similar to those of other Americans, highlighting the potential for DTM to circumvent practical barriers inherent in traditional medical visits (23,24).

Although the American Diabetes Association (ADA) recommends patient-centered management strategies for type 2 diabetes and DTM programs clearly show promise in improving glucose management in underserved populations, there have been no significant efforts to date to *1*) tailor a comprehensive, evidence-based DTM program to meet the needs of H/L patients or *2*) systematically test the efficacy of a tailored DTM program in underserved H/Ls (19,25,26). This study sought to fill critical knowledge gaps by directly comparing an adapted DTM program to comprehensive outpatient management (COM).

Research Design and Methods

This comparative effectiveness RCT enrolled 240 adult (aged ≥18 years) H/L patients with a diagnosis of type 2 diabetes. Patients were randomized to DTM, which used digital devices to share information between patients, caregivers, and clinicians, or COM, the most frequently used option for managing type 2 diabetes patients in the United States. Both comparators were consistent with recommendations in the ADA's *Standards of Medical Care in Diabetes—2018* (27).

Our sample size of 240 (120 per group), yielded 80% power to detect a 0.5% difference in the pre-/post-intervention change in A1C (using a two-tailed *t* test with $\alpha = 0.05$) over 6 months. Our power calculation was based on the meta-analysis by Polisena et al. (12). We computed a sample size–weighted median of 12 SDs for A1C, yielding a value of 1.2%.

Given the SD of the pre-/post-intervention 6-month change in A1C of 1.2% in each group, a 0.45% difference in this 6-month change yields an effect size (ES) of 0.42. This ES is realistic, falling between two sets of reductions in the literature: the Diabetes Control and Complications Trial (in which a 1% decline in A1C reduced microvascular complications by 30%) (28), and RCTs/meta-analyses citing reductions of 0.3% as "clinically significant" (9–13). Falling between these limits, our reduction of 0.45% was clinically significant/meaningful because patients could see improvements in their A1C values.

Patients were followed for 6 months. To minimize resentful demoralization (the perception that the group receiving the new technology [tablet and Bluetooth-enabled peripherals] was getting the "better" treatment), we used the Zelen randomized consent form approach (29). Although a traditional RCT is the study design of choice for most interventions, the Zelen approach is particularly useful in studies of lifestyle interventions, which are often subject to factors such as patient preference and nonadherence (30–32).

Patients were enrolled in the study at nine endocrinology and primary care outpatient practices and an outpatient practice at a large safety-net hospital in the New York Metropolitan Area from September 2019 to August 2022 by bilingual, culturally congruent enrollment specialists. Before the COVID-19 pandemic, all patients were approached in person during visits to one of the designated clinic sites. After a 4-month pause in recruitment because of COVID-19 safety concerns, the study switched to telephone recruitment.

It was not feasible to blind the research nurse to patient participation in the DTM or COM group. To limit selection bias and ensure true random selection, our Biostatistics Unit used a random number generator to randomly select 400 patients from the pool of 4,092 eligible patients.

Eligible patients were approached (or called) for consent to have longitudinal data collected, including surveys at specified time points over 6 months of

participation. Patients who were approached in person signed consent forms; those approached by telephone gave verbal consent.

Team members obtained randomization numbers from the Biostatistics Unit for patients to determine whether they were allocated to the DTM arm or COM arm. For patients randomized into the DTM are, the recruiter approached them to obtain a second consent to receive DTM. Informed consent included a detailed description at a fourth-grade reading level, in the patient's preferred language, of study, risks, and benefits, as well as images of the equipment to be used.

Both comparator cohorts received a phone call from enrollment specialists within 72 hours of enrollment to schedule baseline surveys and blood work, if needed. Enrollment was conducted in patients' language of choice (English or Spanish). Patients were reimbursed $50 for completing surveys and blood work at baseline and 6 months.

Patients randomized to DTM, in addition to comprehensive outpatient visits, received an U.S. Food and Drug Administration–approved computerized monitoring device (Health Recovery Solutions), connecting them through a wireless tablet loaded with Health Recovery Solutions PatientConnect software, as well as eight diabetes educational videos developed by The Permanente Medical Group, Inc. Patients also received a Bluetooth-enabled glucose meter, blood pressure cuff, and weight scale and had weekly nursing telehealth visits with a culturally congruent nurse.

DTM included three main components: *1*) daily self-monitoring of vital signs, *2*) weekly telehealth visits with a nurse, and *3*) eight educational videos, with the goal of building knowledge and diabetes self-efficacy. These videos were vetted by our Community Advisory Board to ensure representation of the language, foods, and culture of our patient population. All components were delivered in patients' language of choice (English or Spanish).

Patients were trained by the enrollment specialists and nurses to use the Health Insurance Portability and Accountability Act–compliant tablet and Bluetooth-enabled peripherals to measure daily vital signs in English or Spanish. The nurse reinforced measurement of daily vital signs during weekly visits. If data (e.g., blood glucose and blood pressure) were significantly outside the normal range, the nurse could initiate a telehealth visit and/or either contact the patient's practitioner to discuss or revise the treatment plan, including medication adjustment (e.g., insulin) or, for urgent matters, instruct the patient to call 911. An enrollment specialist delivered equipment to each patient's home and trained the patient and/or caregiver to use the tablet and peripherals. If technological problems arose or if the patient needed further training that could not be accomplished over the phone, the enrollment specialist would return to the home for additional training.

DTM patients were scheduled to attend weekly video telehealth visits with the nurse, during which vital signs, symptoms of hypoglycemia and hyperglycemia, and behaviors (e.g., food choices) were discussed, as well as the diabetes management videos. The first telehealth visit was designed to facilitate a trusting relationship between the patient and provider, to discuss whether concepts should be reviewed in English or Spanish, and to reinforce the use of the tablet.

Patients were given unlimited access to the diabetes educational videos and asked to view one of the eight videos per week. The nurse reviewed each video with patients during weekly visits; key concepts were reinforced using the teach-back method (33). Each video was presented as one of three types: learn/aprenda, do/actúe, or succeed/triunfe. (Supplementary Appendix S1)

COM, an evidence-based best practice based on the ADA's 2018 Standards of Care (27), is the most frequently experienced option for patients with type 2 diabetes in the United States. COM includes a review of personal and family medical history, social history, medications, screenings, physical examination, and laboratory assessments (27). Patients are instructed to monitor their blood glucose levels within their physician's recommendations and to have routine clinic visits every 3 months.

Patients randomized to COM, in addition to comprehensive outpatient visits, received a glucose meter (ReliOn Premier BLU Blood Glucose Monitoring System), which saves up to 450 test results in memory. To capture all fingerstick tests (beyond 450 values), the enrollment specialist was instructed to reset the monitor every 90 days to allow for continued monitoring and capturing of data. COM patients also received ReliOn Prime blood glucose test strip, a ReliOn lancing device, and ReliOn 33-gauge lancets. Supplies received by each patient were in accordance with physician recommendations regarding the frequency of blood glucose testing. COM

patients also received monthly phone calls regarding their health care utilization.

Six months into enrollment, the New York Metropolitan Area became the epicenter of the COVID-19 epidemic, and H/L residents suffered from disproportionately high rates of hospitalization and death related to severe acute respiratory syndrome coronavirus 2 infection (34). The pandemic necessitated adapting enrollment processes to ensure patient and staff safety. New enrollments were paused for 4 months (from 9 March to 7 July 2020). The 43 patients who were enrolled before 9 March 2020 remained in the study, receiving contactless delivery of supplies. DTM patients continued to receive telehealth visits, and COM patients continued to receive monthly phone calls. Enrollment at the 10 sites resumed on 7 July 2020 but was conducted by phone to ensure safety. A substudy was published on the impact of the COVID-19 pandemic on subjects enrolled in this study (35). Unfortunately, after the pandemic began, adherence data from COM group participants' glucose meters could not be collected because entering their homes was deemed unsafe.

Analytical and Statistical Approaches

This RCT was based on the intention-to-treat (ITT) principle that included all subjects randomized. Outcomes included A1C (the primary outcome); diabetes quality of life (measured with the Diabetes Quality of Life Brief Clinical Inventory (36); blood pressure; weight; medication adherence (measured with the Adherence and Refill Medication Scale [ARMS–D] (37); hypoglycemia episodes, diabetes self-efficacy (measured with the Stanford Diabetes Self-Efficacy Scale [DSES] (38); emotional functioning (measured with the five-item validated Problem Areas in Diabetes [PAID-5] questionnaire (39); inpatient utilization; unscheduled type 2 diabetes physician visits; and sick days. Data were analyzed using SAS, v. 9.4, statistical software (SAS Institute, Cary NC).

Usability variables of adherence and engagement included *1*) patient adherence to vital signs measurement, including blood pressure, blood glucose, and weight; *2*) total number of telehealth visits completed (maximum 25); *3*) patient and caregiver usability, measured with the Telemedicine Satisfaction and Usefulness Questionnaire (40); *4*) caregiver app utilization (for patients with caregivers); *5*) patient and caregiver engagement with technology; and *6*) patient engagement in both groups (measured with the 10-item Patient Activation Measure [PAM] [41,42]).

Study data were collected and managed using the REDCap (Research Electronic Data Capture) tool (43). The datasets generated during and/or analyzed in the study are available from the corresponding author upon reasonable request.

The primary objective was to compare change in A1C from baseline to 6 months between groups. We performed an ANCOVA adjusting for caregiver status (yes or no). In keeping with the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, Topic E9, statistical principles for clinical trials (chapter V, section 5.7) with a stratification variable, the interaction term for treatment × caregiver status was included in the primary analysis and as a main effect for treatment and caregiver status (44).

The secondary analysis of A1C over time from baseline to 3 months to 6 months, was analyzed with a mixed-model, repeated-measures ANCOVA adjusting for caregiver status (yes or no). Other variables were analyzed using ANCOVA or, where appropriate, a Mann-Whitney *U* test, as detailed below.

Results

This study conformed to all Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting. As seen in the CONSORT diagram (Supplementary Appendix S2), of 971 patients screened for eligibility, 65 were excluded; the remainder were approached for permission to collect data (n = 906), of which 662 declined. The remaining 244 were randomized to DTM or COM. Because we used the randomized consent design (Zelen) approach, we approached those randomized to DTM for permission to follow them using telehealth, and 120 consented, resulting in 120 randomized to DTM and 120 randomized to COM.

Study groups were equivalent on key baseline variables; 65.4% were female, and the mean age was 55.7 years (range 21–88 years). Most (62.3%) reported having a total household annual income <$25,000, and more than half (51.3%) reported being uncomfortable or very uncomfortable speaking English (Table 1). Most (74%) reported having a high school education or less.

Primary ITT Analysis

For our primary outcome, change in A1C from baseline to 6 months, mean A1C values decreased from 8.32 to 7.55% in the DTM group and from 8.32 to 8.07% in the

TABLE 1 Demographics

Characteristic	Overall	DTM	COM
Sex			
Female	157 (65.4)	81 (67.5)	76 (63.3)
Male	83 (34.6)	39 (32.5)	44 (36.7)
Age, years	56.5 (21–88)	56.1 (27–83)	55.3 (21–88)
Yearly household Income, $			
<25,000	124 (62.3)	57 (58.2)	67 (66.3)
25,000–49,999	41 (20.6)	19 (19.4)	22 (21.8)
50,000–74,999	19 (9.6)	12 (12.2)	7 (6.9)
75,000–100,000	6 (3.0)	5 (5.1)	1 (1.0)
>100,000	9 (4.5)	5 (5.1)	4 (4.0)
Health insurance			
Medicaid	84 (35.0)	40 (33.3)	44 (36.7)
Medicare	62 (25.8)	33 (27.5)	29 (24.2)
Other/refused to answer	58 (24.2)	31 (25.8)	27 (22.5)
No insurance	53 (22.1)	21 (17.5)	32 (26.7)
Private insurance	36 (15.0)	22 (18.3)	14 (11.7)
Education			
Less than high school	69 (29.7)	38 (33.0)	31 (26.5)
Incomplete high school	29 (12.5)	12 (10.4)	17 (14.5)
High school Diploma/GED	76 (32.0)	37 (32.2)	39 (33.3)
Technical school	21 (9.1)	10 (8.7)	11 (9.4)
Associates degree	16 (6.9)	8 (7.0)	8 (6.8)
Bachelor's degree	16 (6.9)	7 (6.1)	9 (7.7)
Postgraduate degree	5 (2.2)	3 (2.6)	2 (1.7)
Diabetes duration, years			
<1	22 (9.5)	10 (8.7)	12 (10.3)
1–5	78 (33.6)	33 (28.7)	45 (38.5)
6–10	33 (14.2)	19 (16.5)	14 (12.0)
>10	99 (42.7)	53 (46.1)	46 (39.3)
Comfort speaking English			
Very uncomfortable	86 (37.1)	44 (38.3)	42 (35.9)
Uncomfortable	33 (14.2)	16 (13.9)	17 (14.5)
Neither uncomfortable nor comfortable	20 (8.6)	11 (9.6)	9 (7.7)
Comfortable	38 (16.4)	17 (14.8)	21 (18.0)
Very comfortable	55 (23.7)	27 (23.5)	28 (23.9)
Marital status			
Married	99 (42.9)	48 (42.1)	51 (43.6)
Single	52 (22.5)	22 (19.3)	30 (25.6)
Divorced	30 (13.0)	18 (15.8)	12 (10.3)
Widowed	20 (8.7)	12 (10/5)	8 (6.8)
Separated	21 (9.1)	9 (7.9)	12 (10.3)
Other	9 (3.9)	5 (4.4)	4 (3.4)
Country of origin			
El Salvador	70 (30.3)	32 (28.1)	38 (32.5)
Puerto Rico	29 (12.6)	15 (13.2)	14 (12.0)
Honduras	23 (10.0)	12 (10.5)	11 (9.4)
Guatemala	19 (8.2)	9 (7.9)	10 (8.6)
United States	17 (7.4)	8 (7.0)	9 (7.7)
Columbia	17 (7.4)	10 (8.8)	7 (6.0)
Mexico	13 (5.6)	6 (5.3)	7 (6.0)
Peru	12 (5.2)	6 (5.3)	6 (5.1)
Ecuador	10 (4.3)	7 (6.1)	3 (2.6)

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TABLE 1 Demographics (Continued)

Characteristic	Overall	DTM	COM
Dominican Republic	10 (4.3)	3 (2.6)	7 (6.0)
Chile	4 (1.7)	2 (1.7)	2 (1.7)
Nicaragua	2 (0.9)	0 (0.0)	2 (1.7)
Cuba	2 (0.9)	2 (1.8)	0 (0.0)
Other	2 (0.9)	1 (0.9)	1 (0.9)
Bolivia	1 (0.4)	1 (0.9)	0 (0.0)

Data are *n* (%) or mean (range). Numbers may not total the total 240 sample size because of missing values in some categories. GED, general education diploma.

COM group. The adjusted mean A1C for DTM minus A1C for COM was −0.42 (95% CI −0.80 to −0.03).

Daily caregiver phone interaction for the DTM and COM groups was 82 and 81%, respectively, and live daily caregiver interaction was 92 and 84%, respectively. Neither caregiver status ($P = 0.37$) nor the between-treatment × caregiver interaction ($P = 0.67$) were significant. We therefore removed the interaction terms, resulting in a model that found a significant study group effect ($P = 0.03$), with DTM showing a significant improvement compared with COM.

Secondary Analyses

Change in A1C over time (from baseline to 3 months to 6 months) was analyzed with mixed-model, repeated-measures ANCOVA. There was a significant group × time interaction ($P < 0.02$) (a significant difference between groups for change in bA1C over time). Specifically, within the DTM group, there was a significant difference with respect to A1C between baseline and month 3 ($P < 0.01$) and between baseline and month 6 ($P < 0.01$) but not between month 3 and month 6 ($P = 1.00$). Within the COM group, there were no significant differences in A1C between baseline and month 3 ($P < 0.59$), between baseline and month 6 ($P < 0.25$), or between month 34 and month 6 ($P = 1.000$) (Figure 1).

For blood pressure, a mixed-model, repeated-measures ANCOVA showed a decrease over 6 months in mean systolic blood pressure of 8.7 mmHg in the DTM group compared with an increase of 2.4 mmHg in the COM group ($P = 0.01$). Mean diastolic blood pressure decreased by 3.2 mmHg in the DTM group compared with an increase of 1.0 mmHg in the COM group ($P = 0.03$).

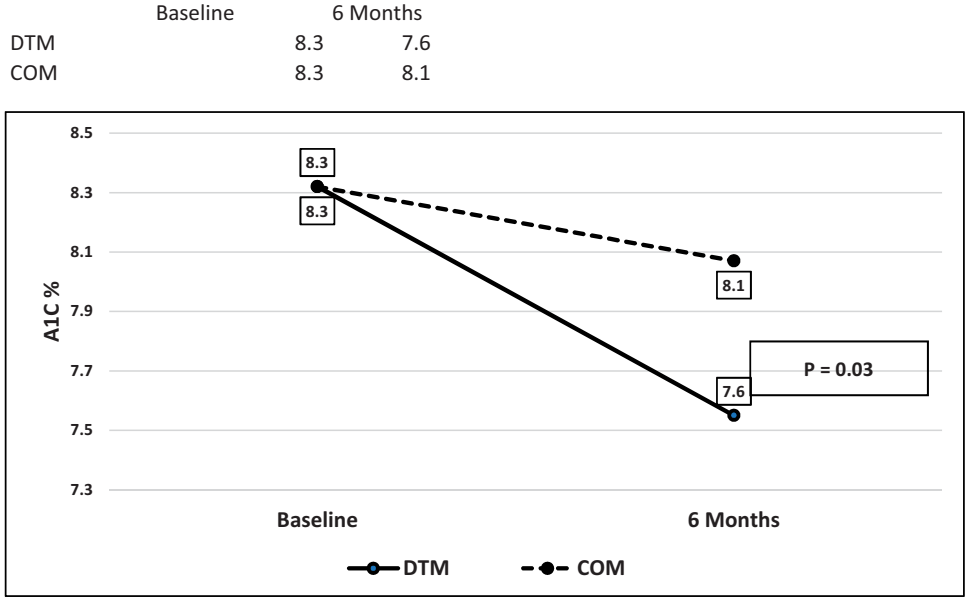

FIGURE 1 Changes in A1C over time for the DTM and COM groups.

The percentage decrease of systolic blood pressure ≥ 10 mmHg (which ADA guidelines associate with a significant drop in mortality) was also significantly different between groups (DTM 43.0% vs. COM 16.3%, $P < 0.01$) (45). Similarly, the percentage decrease of diastolic blood pressure ≥ 5 mmHg (also associated with a significant drop in mortality) was significantly different between groups (DTM 47.7% vs. COM 18.6%, $P < 0.01$) (45) (Table 2).

Hypoglycemia episodes (defined as blood glucose <70 mg/dL, measured by fingerstick or reported symptoms), was analyzed using a Mann-Whitney nonparametric *U* test. Medians were 3 and 2 hypoglycemic events, for the DTM and COM groups, respectively, yielding a *P* value of 0.1796, indicating no significant between-group difference.

On ARMS-D scores, there were no significant differences found in 6-month mean difference between groups (DTM −0.15 vs. COM −0.26, $P = 0.53$) or between 6-month scores (DTM 14.1 vs. COM 14.8, $P = 0.18$).

On the DSES, scores in the DTM group increased from 7.3 at baseline to 8.2 at 6 months ($P < 0.01$), and scores in the COM group increased from 7.6 at baseline to 8.0 at 6 months ($P = 0.19$). However, self-efficacy was not significantly different between groups; change in DSES from baseline to 6 months was 0.83 in the DTM group versus 0.28 in the COM group ($P = 0.07$) (Table 3).

Between-group differences in DQOL scores were not significant ($P = 0.65$); scores decreased (i.e., quality of life improved) over the 6-month period for the DTM and COM groups by 3.1 and 2.5, respectively.

For changes in weight from baseline to 6 months, the DTM group lost a mean 2.4 lb, whereas the COM group gained a mean 0.1 lb ($P = 0.13$).

For emotional functioning, analysis of scores on the PAID-5 scale (39) found no significant differences between groups between baseline and 6 months. Both groups scores improved almost identically (DTM −2.2 and COM −2.1, $P = 0.75$).

Tertiary Analyses: Health Care Utilization

There were 73 inpatient utilization records of encounters from 50 unique patients, of which 35 records were emergency department (ED) visits and 38 were hospitalizations. The mean number of ED visits was 0.17 (median 0, range 0–3). The mean number of hospitalizations was 0.13 (median 0, range 0–4).

In the DTM group, 23 patients were hospitalized for a total of 109 days (mean 4.74 days); in the COM group, 26 patients were hospitalized for a total of 107 days (mean 4.12 days). The DTM group had 20 hospitalizations, whereas the COM group had 18. There was no significant difference between groups with respect to the proportion of patients who had at least one hospital visit (DTM 10.83% vs. COM 10.92%, $P < 0.9820$).

The DTM group experienced 20 ED visits, whereas the COM group had 15 ED visits. There was no significant difference between groups for the proportion of patients who had at least one ED visit (DTM 11.67% vs. COM 10.92%, $P < 0.8562$). There were also no statistically significant differences for cumulative lengths of stay as determined by the Mann-Whitney *U* test.

Unscheduled sick visits and sick days were assessed monthly through self-report and analyzed using χ^2 tests comparing group rates. The proportion of patients who reported at least one sick day was significantly different between the DTM and COM groups (22 [18.3%] and 6 [5%], respectively, $P = 0.0013$).

For blood glucose monitoring (BGM), the majority of participants in the DTM group (64.2%) were highly

TABLE 2 Systolic and Diastolic Blood Pressure Reductions for DTM Versus COM Groups

Study Group	Significant SBP Decline ≥10 mmHg	No Significant SBP Decline	Total	*P*
DTM	37 (43.0)	49 (57.0)	86	<0.01
COM	7 (16.3)	36 (83.7)	43	
Study Group	**Significant DBP Decline of ≥5 mmHg**	**No Significant DBP Decline**	**Total**	***P***
DTM	41 (47.7)	45 (52.3)	85	<0.01
COM	8 (18.6)	35 (81.4)	43	

Data are *n* (%) or *n*. A total of 111 of the 240 participants lacked one or both of the blood pressure measurements (baseline and follow-up); 175 participants had baseline data, 155 had follow-up data, and 129 had both baseline and follow-up data). DBP, diastolic blood pressure; SPB, systolic blood pressure.

TABLE 3 Medication Adherence, Self-Efficacy, Quality of Life, Weight, and Emotional Functioning for DTM (n = 120) Versus COM (n = 120) Participants

Study Group	Participants With Data Available, *n*	Participants With Data Missing, *n*	Mean ± SD	Median (Range)	*P*
Adherence to medication (ARMS-D score)					
DTM					0.53
At baseline	89	31	14.4 ± 3.8	13 (11–28)	
At 6 months	88	32	14.1 ± 3.9	12.5 (11–28)	
Difference in score	66	54	−0.15 ± 3.5	0.0 (−9 to 10)	
COM					
At baseline	97	23	14.9 ± 5.2	13 (11–34)	
At 6 months	100	20	14.8 ± 4.3	13 (7–29)	
Difference in score	86	34	−0.26 ± 4.2	0.0 (−22 to 9)	
Diabetes self-efficacy (DSES score)					
DTM					0.07
At baseline	93	27	7.3 ± 1.7	7.4 (3–10)	
At 6 months	77	43	8.2 ± 1.3	8.5 (4–10)	
Difference in score	70	50	0.83 ± 1.7	0.63 (−6 to 6)	
COM					
At baseline	94	26	7.6 ± 1.6	7.8 (4–10)	
At 6 months	96	24	7.9 ± 1.8	8.2 (2–10)	
Difference in score	85	35	0.28 ± 1.5	0.25 (−5 to 4)	
Quality of life (DQOL score)					
DTM					0.65
At baseline	115	5	32.0 ± 9.1	32.0 (13–57)	
At 6 months	90	30	27.9 ± 7.0	27.0 (15–49)	
Difference in score	89	31	−3.11 ± 8.2	−3.00 (−22 to 16)	
COM					
At baseline	117	3	33.7 ± 9.8	33 (13–60)	
At 6 months	104	16	30.9 ± 8.6	29.5 (8–50)	
Difference in score	103	17	−2.46 ± 9.5	−1.00 (−21 to 22)	
Weight, lb					
DTM					0.13
At baseline	95	25	182.1 ± 39.8	174 (119–294)	
At 6 months	85	35	177.4 ± 37.7	172 (115–285)	
Difference in weight	79	41	−2.41 ± 8.0	−1.80 (−23 to 17)	
COM					
At baseline	73	47	180.4 ± 35.4	180 (107–263)	
At 6 months	65	55	180.1 ± 44.1	172 (117–393)	
Difference in weight	44	76	0.07 ± 6.6	0.50 (−15 to 12)	
Emotional functioning (PAID-5 score)					
DTM					0.75
At baseline	115	5	9.0 ± 6.0	9 (0–20)	
At 6 months	90	30	6.7 ± 5.8	5.5 (0–18)	
Difference in score	89	31	−2.19 ± 5.3	−2.00 (−14 to 15)	
COM					
At baseline	117	3	9.7 ± 6.3	10 (0–20)	
At 6 months	103	17	7.3 ± 6.1	6 (0–20)	
Difference in score	102	18	−2.09 ± 5.3	−2.00 (−19 to 10)	

Descriptive statistics are based on raw data. All *P* values were obtained from mixed-model analysis.

adherent (performing 91–180 measurements over 6 months); 6.7% were moderately adherent (46–90 measurements), 5.8% were minimally adherent (1–45 measurements), and 23.3% were nonadherent (0 measurements). For blood pressure monitoring, the majority of participants (62.5%) were highly adherent, with

moderate, low, and nonadherence rates of 8.3, 5.8, and 23.3%, respectively. Most patients (51.7%) were highly adherent in weight monitoring. The proportions of patients with moderate, low, and nonadherence rates were 13.3, 11.7, and 23.3%, respectively.

The proportion of weekly scheduled telehealth visits that were kept was 83% (20.7 of 25). The average length of a visit was 38.1 minutes (range 1.6–113.9 minutes). The mean number of minutes spent per patient watching the eight educational videos was 1:46 minutes/week. Videos were relatively short in length, ranging from 1:17 to 3:00 minutes each.

The mean Telemedicine Satisfaction and Usefulness Questionnaire score (>56 is considered a good experience score for patients) for the 65 respondents was 63.1 ± 5.95, and the median score was 64 (range 48–70). Overall, 75.4% of respondents had a score >56. Baseline PAM scores were 65.3 for the DTM group and 65.2 for the COM group ($P = 0.74$). At 6 months, PAM scores decreased to 60.2 and 62.4, respectively ($P = 0.35$).

Discussion

Participants in the DTM group achieved significant reductions in A1C and improvements in self-efficacy and systolic and diastolic blood pressure over the 6-month study period compared with those in the COM group. This is the first study to exclusively enroll underserved H/L patients in an RCT to receive either DTM or COM.

These findings are consistent with those of the IDEATel Study, although over a much shorter time frame than in the IDEATel study, in which patients were managed over a 5-year period (20,21). Both studies included all patients diagnosed with type 2 diabetes, without regard to their degree of blood glucose control. The IDEATel study enrolled underserved patients identifying as White, Black or Latino, and a prerequisite for study enrollment was insurance coverage (i.e., current Medicare beneficiaries); however, the current study exclusively enrolled H/L patients, many of whom were uninsured.

Access issues this population typically faces may have been at least partially addressed by the nature of the DTM intervention; even during the height of the COVID-19 pandemic, which severely affected underserved H/Ls in New York, patients randomized to DTM were able to safely meet with the study nurse to address their self-management of diabetes.

For our primary outcome, A1C, patients receiving DTM experienced significant glycemic improvement after 3 months of intervention and sustained that improvement until the end of the 6-month study. This improvement may have been the result of high rates of adherence, the development of diabetes-related self-efficacy, and the rigorous adaptation process to ensure the feasibility and acceptability of the intervention during the first year of the study.

To identify patient-reported factors that likely had an impact on patient adherence and ultimately, improvement in self-efficacy, A1C, and blood pressure, we conducted semi-structured, 1:1 interviews with 42 patients after they completed the 6-month DTM intervention. These interviews were conducted by phone in each patient's language of choice (Spanish or English). A qualitative analysis of participant feedback identified the factors patients reported contributed to their success. With the guidance of the culturally congruent nurse, patients reported "feeling supported" and becoming mindful of their own role in taking care of their health and diabetes. As one patient reported:

> *"I tell you that, at first, I didn't take it [the diabetes] seriously . . . , I'm diabetic. I don't eat this and that, and that's it. Or, if I eat more of this, I put more insulin on, and that's it. That was my thinking . . . . One has to control this from the beginning so as not to suffer greater consequences."*

Bandura (46) defined self-efficacy as "people's belief in their ability to control their functioning and events that affect their lives," emphasizing that self-efficacy can facilitate motivation, well-being, and personal accomplishment. He further posited that people's beliefs in their efficacy are influenced by four primary sources, including mastery experiences, vicarious experiences, social persuasion, and emotional states. The DTM intervention incorporated all of these sources of influence; the culturally congruent educational videos portrayed people who looked like the participants succeeding in managing their diabetes. Social persuasion was provided by the culturally congruent nurse, who provided positive reinforcement to patients every week. As one patient reported:

> *"La diabetes no me controla a mí, sino que yo tengo que controlar la diabetes." ("Diabetes does not control me, but I have to control [my] diabetes.")*

Patients in the DTM group achieved high rates of adherence for blood glucose, weight, and blood pressure monitoring. This finding may have been the result of the education provided by culturally congruent

recruitment specialists and nurses in patients' homes, in their preferred language, and scheduled at convenient times, including nights and weekends).

Other studies affirm that people with higher diabetes self-efficacy experience improvements in glycemic control, medication adherence, and quality of life (47–49). Telemedicine has also emerged as a way to use technology to help improve patient self-efficacy (50). This study confirms that underserved H/L people with diabetes note only are receptive to using telemedicine, but also experience improved glycemic control and better adherence to management plans when telemedicine is used (51–54). For our DTM-specific secondary clinical outcome measures, systolic and diastolic blood pressure, improvements may also have been the result of a high level of adherence to vital sign monitoring; Individuals in the COM group experienced an increase in both systolic and diastolic blood pressure. Observed differences in blood pressure are consistent with significant decreases in mortality found in predictions of major adverse cardiac events (45).

The 2017 systematic review by McCurley et al. (19) of culturally tailored interventions to better reach the high-risk Hispanic population found that interventions with the largest effect sizes tended to incorporate literacy modification, Hispanic foods/recipes, cultural diabetes beliefs, family/friend participation, structured community input, and innovative experiential learning. All of these factors were incorporated into the DTM intervention. Similarly, the teach-back education method was used to ensure that patients understood concepts presented in the culturally congruent educational videos.

Our use of the adaptation framework of Wingood and DiClemente (55) to systematically adapt the home telemonitoring intervention for people type 2 Diabetes in underserved H/L communities ensured a comprehensive approach that addressed many aspects and perspectives that might be otherwise have been missed when caring for this population. For example, offering visits outside of the typical 9-5 workday (many patients reported working two or three jobs and therefore being unable to participate in visits during usual work hours), discussing culturally relevant food selections (i.e., American vs. Caribbean or South American eating patterns), and using familiar terminology (e.g., "azucar" [sugar] rather than "glucosa" [glucose] when referring to blood glucose) were key factors that likely made a difference, as was the provision of educational videos that presented people who looked like the intervention's participants successfully managing their diabetes.

Limitations

This study faced a number of limitations. Because of the COVID-19 pandemic, we were unable to safely visit the homes of COM participants to obtain blood glucose monitoring adherence data from their glucose meters. Therefore, we have no way of knowing whether these free supplies affected adherence rates. This limitation may explain why we saw minor (nonsignificant) improvements in quality of life QoL and A1C in the COM group. Missing data were an issue throughout the study in both groups. Finally, it is difficult to ascertain the impact of the COVID-19 pandemic on other outcomes. Although these results are highly encouraging, it is important to replicate the study with additional underserved patient panels.

Conclusion

This adapted DTM intervention achieved clinically and statistically significant reductions in A1C, diabetes self-efficacy, and blood pressure over the 6-month study period compared with COM. The process of adaptation, along with consistent culturally congruent support, are likely to have been crucial components of the intervention's success. These highly encouraging results must be replicated in larger samples of similar populations.

ACKNOWLEDGMENTS

The authors acknowledge Jill Cotroneo of Northwell Health for administrative support and the individuals who generously volunteered their time to participate in this study.

FUNDING

This project was funded by the Patient-Centered Outcomes Research Institute (AD-2017C3-9185).

DUALITY OF INTEREST

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

AUTHOR CONTRIBUTIONS

All authors reviewed and edited the manuscript. R.P. wrote the manuscript and was responsible for study conceptualization, funding acquisition, methodology, project administration, implementation, and supervision. S.M. contributed to study conceptualization, methodology, and implementation. V.C.G., J.M., and N.G. contributed to implementation, patient consent, and data management. M.S.W. coordinated with the institutional review board and contributed to implementation, methodology, and data management. E.C. contributed to implementation, patient consent, data

management, and data analysis. C.N.N. wrote the manuscript and contributed to data management and data analysis. V.H.P. contributed to implementation, methodology, and data analysis. A.K.M., D.G., L.F.M., J.G., A.N.M., S.I.M., R.Z., M.P., J.P., R.J.D., A.B.-Y., C.E., M.M., and W.G. contributed to the methodology. P.B. contributed to implementation. C.S. and M.K. contributed to the data analysis. M.L.L. contributed to methodology and data analysis. L.B. contributed to implementation and methodology. N.Z. contributed to implementation and patient consent. Y.T.H. wrote the manuscript and contributed to conceptualization and methodology. C.N.N. is the guarantor of this work and, as such, had full access to all data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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