

# Randomized Controlled Trial of Technology-Assisted Case Management in Low-Income Adults with Type 2 Diabetes

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## Abstract

**Objective:** To assess the efficacy of technology-assisted case management (TACM) with medication titration by nurses using guideline-based algorithms, under physician supervision in improving glycemic control in low-income rural adults with poorly controlled type 2 diabetes.

**Research Design and Methods:** Adults (aged  $\geq 18$  years) from the southeastern United States with hemoglobin A1c [HbA1c]  $\geq 8\%$  were randomized to TACM or usual care. Evidence-based guidelines were used to develop medication titration algorithms in conjunction with clinic physicians. Participants were given a telehealth device that uploaded blood glucose and blood pressure readings daily to a central server. A nurse case manager was trained on the algorithms and authorized to titrate medications every 2 weeks based on the algorithm under the supervision of an internist and an endocrinologist. Participants were assessed at baseline, 3 months, and 6 months. The primary outcome was HbA1c at 6-months postrandomization in the intent-to-treat (ITT) population.

**Results:** One hundred thirteen participants were randomized to either TACM intervention or usual care. Based on ITT population after multiple imputation, the analysis of covariance with baseline HbA1c as covariate showed that HbA1c at 6 months for TACM was significantly lower compared to the usual care group ( $-0.99$ ,  $P=0.024$ ). Moreover, longitudinal mixed effects analysis suggested that the rate of decline in HbA1c over time for TACM was significantly faster compared to the usual care group ( $-0.16$ ,  $P=0.038$ ). Results based on per-protocol population were similar.

**Conclusions:** Technology-assisted case management by a nurse with medication titration under physician supervision is efficacious in improving glycemic control in low-income rural adults with poorly controlled type 2 diabetes.

**Keywords:** Diabetes technology, Telemedicine, Case management.

## Introduction

OVER 29 MILLION people in the United States have diabetes, which is more than 9% of the total population.<sup>1</sup> Diabetes is the seventh leading cause of death, with higher prevalence and incidence in racial and ethnic minority groups.<sup>1,2</sup> Evidence suggests that individuals residing in rural areas have a higher prevalence ( $\sim 17\%$ ) of diabetes compared to residents of urban areas.<sup>3</sup> Diabetes is associated with significant morbidity, mortality, increased healthcare utili-

zation, and increased healthcare costs, accounting for an estimated \$245 billion in total expenditures annually.<sup>2</sup> Serious health complications such as cardiovascular disease, stroke, renal disease, blindness, lower limb amputations, and premature death are associated with poorly controlled diabetes.<sup>2</sup>

In South Carolina, where diabetes ranks seventh highest in the nation, one in eight adults has diabetes, and  $\sim 79\%$  of the adults with diabetes have comorbid hypertension.<sup>4,5</sup> Approximately one in six African American adults in South Carolina has diabetes, compared to one in nine White

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American adults, and one in five adults in South Carolina with an annual household income less than \$15,000 has diabetes.<sup>4</sup> In 2014, hospital costs related to diabetes increased 60%, resulting in more than \$400 million in hospital charges secondary to diabetes complications in South Carolina,<sup>5</sup> a number expected to exceed \$4 billion by the year 2020.<sup>4</sup>

Most of the observed differences in diabetes-related outcomes such as glycemia, blood pressure, and lipid control, and resource utilization, are due to patient level factors.<sup>6–11</sup> Nurse case management has been shown to have a positive impact on chronic disease management, including patient level factors such as self-management, treatment adherence, and lifestyle modifications that result in improved glycemic control among patients with type 2 diabetes.<sup>12–19</sup> Similarly, advances in technology present new opportunities for providers to support their patients with diabetes between face-to-face visits. There is a growing body of evidence to suggest that telemonitoring interventions, especially when combined with active care management, offer effective strategies for improving metabolic control in patients with diabetes.<sup>13,20–23</sup> Few studies, however, have tested the effectiveness of technology-assisted case management in low-income predominantly rural populations. Therefore, the objective of this study was to assess the efficacy of technology-assisted case management (TACM) with medication titration by nurses using guideline-based algorithms, under physician supervision in improving glycemic control in low-income rural adults with poorly controlled type 2 diabetes. We hypothesized that the TACM intervention will be superior to usual care in terms of reductions in hemoglobin A1c (HbA1c) at 6 months of follow-up.

## Research Design and Methods

### *Study design and participants*

The study design used for this investigation was a randomized controlled trial (RCT) with a follow-up period of 6 months, for which the protocol has been previously published.<sup>24</sup> The study assessment visits were at baseline, 3 months, and 6 months postrandomization. The population of interest was low-income rural adults with poorly controlled type 2 diabetes residing in coastal South Carolina and served at Federally Qualified Healthcare Centers (FQHCs). The participants were recruited from eight community-based adult medicine primary care practices within the Franklin C. Fetter Family Health Centers, Inc.—downtown Charleston, Summerville Health Center, Low Country Pediatrics and Adults, Enterprise Health Center, Cross Health Center, Hollywood, Walterboro, and John's Island.

Participants were recruited based on the following: (1) International Classification of Diseases (ICD-9 codes) consistent with a diagnosis of type 2 diabetes from clinic billing data and laboratory data and (2) referrals from physicians, other clinic staff such as nurses, or patients themselves. Letters of invitation signed by the patients' primary care providers were mailed to patients, and international review board (IRB) approved recruitment flyers were posted in prominent locations within the study clinics. Among participants who were interested in participating in the study, only those that were (1) 18 years of age or older, (2) were receiving care within the Franklin C. Fetter Family Health Center, (3) had a clinical diagnosis of type 2 diabetes and HbA1c  $\geq 8\%$  at screening, (4) were willing

to use the innovative FORA 2-in-1 telehealth system, (5) had a working landline for the duration of the study, and (6) were able to communicate in English were eligible to participate in the study. Patients were excluded if they showed mental confusion on interview suggesting significant dementia, were participating in other diabetes clinical trials, had alcohol or drug abuse/dependency, had active psychosis or acute mental disorder, had a life expectancy  $< 6$  months, or were pregnant and/or lactating females. Participants received \$25 for completing baseline materials, \$25 for the 3-month assessment, and \$25 for the 6-month assessment.

All study procedures were approved by the Medical University of South Carolina IRB. A partial waiver for Health Insurance Portability and Accountability Act was also approved for use of clinical records. All participants gave an informed consent to be enrolled in the study.

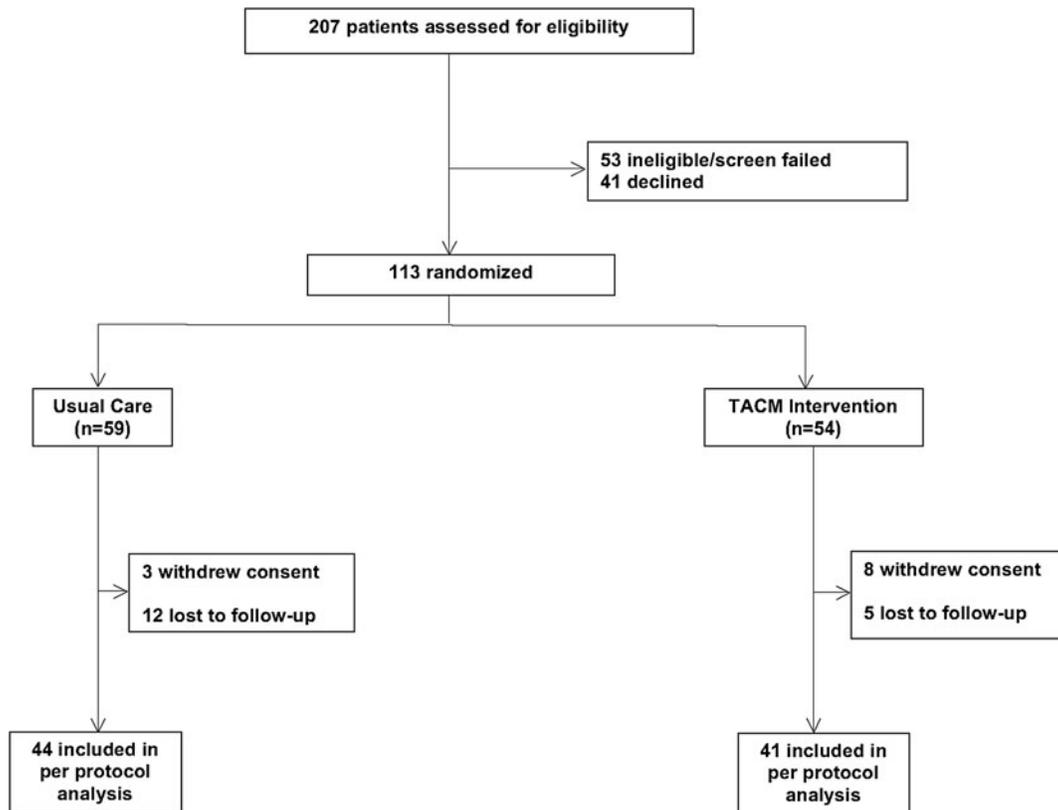
### *Randomization and blinding*

The nurse case manager verified inclusion and exclusion criteria for all participants before randomization (1:1) to one of the two study groups. The randomization was performed in waves such that  $\sim 50$  participants were randomized every 6 months. The randomization sequence was web-based computer generated and was accessible to the nurse case manager, but remained confidential to all study sites. Research assistants collecting primary data on the participants were blinded to treatment assignments to prevent bias in the evaluation of outcomes. The only member of the research team that was not blinded was the nurse case manager delivering the intervention. Participants and treating physicians were not blinded because of the nature of the intervention.

### *Procedures*

In this RCT, the two study groups were the Technology-assisted Case Management (TACM) intervention group and the usual care group. The TACM group used the FORA 2-in-1 telehealth system for diabetes management to link a case manager to patients with poorly controlled type 2 diabetes in real time. The FORA system is an inexpensive, off-the-shelf, state-of-the-art technology that comprises an easy to operate 2-in-1 blood glucose and blood pressure monitor that uploads results to a secure website through a modem. Patients in the TACM group were asked to provide measurements on blood glucose and blood pressure once a day using the FORA system. A trained full-time registered nurse was responsible for teaching participants how to use the FORA device and problem solving around the device. Based on FORA measurements and an evidence-based treatment algorithm approved by the FQHC primary care providers, the nurse case manager made medication adjustments weekly (for patients on insulin) or biweekly (for patients on oral agents) under the supervision of the study physicians (Dr. Leonard Egede, an internist, and Dr. Jyotika Fernandes, an endocrinologist).

The usual care group received the current standard of care at the study clinics. More specifically, the providers were responsible for determining treatment parameters, making changes in the treatment regimen, or determining follow-up visits, in addition to the study visits. Contact between the scheduled visits was patient initiated, and clinic nurses were used to follow-up on problematic patients or patients with abnormal results.



**FIG. 1.** Trial profile (CONSORT Diagram). TACM, technology-assisted case management.

To ensure treatment was completely administered in accordance with the study protocol, 20% of the intervention study charts was randomly selected and reviewed along with the FORA uploads for the corresponding patients. Rating forms were developed to assess if the nurse case manager titrated medications appropriately and to tell how well they accomplished a range of relevant tasks for each patient. Given the intensity of the intervention protocol, optimal level of compliance was ensured by (1) stressing (at enrollment) the importance of daily testing and uploading of data using FORA; (2) placing weekly telephone calls to remind participants to test and upload FORA measurements; (3) requesting names and telephone numbers of three relatives who could readily and easily contact the participant if needed and/or requested by study staff; (4) being flexible in accommodating participants' schedules; and (5) providing monetary reimbursement.

#### Primary outcome

HbA1c was measured at baseline, 3 months, and 6 months. The primary outcome of interest was HbA1c level measured from blood specimens drawn at 6-month follow-up. TACM treatment efficacy was suggested by a significantly greater reduction in HbA1c at 6-month follow-up compared to usual care. This article is focused on reporting the results of the primary outcome analyses as indicated in our protocol article.<sup>24</sup>

#### Statistical analysis

Based on power and sample size calculations for differences in longitudinal trajectories in levels of HbA1c (base-

line, 3 months, and 6 months), 80 subjects were needed in each intervention group to have 85% power to detect at least 0.4 standardized effect size between TACM and usual care (assuming level of significance of 0.05 and intraclass correlation coefficient  $\rho > 0.6$ ). Therefore, the total sample size needed for the per-protocol (PP) analysis was 160 subjects. After accounting for a total of 20% dropout, the sample size required for the intent-to-treat (ITT) analysis was 200 subjects (100 in each group).

For all randomized patients, descriptive statistics was calculated overall and by treatment group for demographic characteristics, clinical, and other prognostic variables at baseline. We compared results for imbalance across the two treatment groups (TACM and usual care) to identify potential confounders to be used for adjustment in subsequent analyses (chi-square test for categorical variables and *t*-test for continuous variables).

Primary analyses were performed on the ITT population comprising all randomized participants. Missing data were imputed using multiple imputation (MI). MI on missing HbA1c values was performed under the assumption of missing at random using PROC MI (Markov chain Monte Carlo method), and results were combined for final inference using PROC MIANALYZE using Rubin's rule (SAS version 9.4, North Carolina). The variables used in the imputation model were gender, age, marital status, race, insured (versus not insured), body mass index (BMI), education, smoking, diabetes duration, depression, number of comorbidities, social support, and literacy.

First, we performed an analysis of covariance (ANCOVA) on the ITT data after imputation with baseline levels of

HbA1c as covariate, to determine if there was a significant difference in baseline-adjusted levels of HbA1c at 6-month follow-up between TACM and usual care. In addition, we performed a longitudinal linear mixed effects analysis to compare trajectories of HbA1c levels over time between

TABLE 1. BASELINE SAMPLE DEMOGRAPHICS BY TREATMENT GROUP

Variable	All (n=113)	Usual care (n=59)	TACM (n=54)	P
Men	18.6	18.6	18.5	0.986
Age (years)				0.889
21-49	29.2	32.2	25.9	
50-55	20.4	18.7	22.2	
56-59	16.8	17.0	16.7	
60+	33.6	32.1	35.2	
Race				0.104
White	21.2	22.0	20.4	
Black	75.2	78.0	72.2	
Other	3.6	0.0	7.4	
Married	32.7	35.6	29.6	0.500
Education				0.337
<HS	20.4	25.4	14.8	
HS graduate	46.9	45.8	48.2	
>HS	32.7	28.8	37.0	
Income				0.913
\$<10,000	36.3	33.9	38.9	
\$<15,000	27.4	28.8	25.9	
\$<25,000	27.4	27.1	27.8	
\$25,000+	8.9	10.2	7.4	
Insured	46.9	52.5	40.7	0.209
Work status				0.390
Working	33.6	40.7	25.9	
Retired	15.0	13.6	16.7	
On disability pay	24.8	23.7	25.9	
Other	26.6	22.0	31.5	
Fair/poor health	60.2	57.6	63.0	0.563
Smoker				0.902
Yes	53.1	52.5	53.7	
Vigorous/moderate (days/week)				0.560
Never	23.9	23.7	24.1	
1-2	40.7	35.6	46.3	
3-4	23.9	28.8	18.5	
5+	11.5	11.9	11.1	
Charlson index	11.7±2.4	11.7±2.3	11.7±2.5	0.958
Age (years)	54.2±11.0	53.4±10.5	55.1±11.4	0.427
Years of education	12.2±2.4	11.9±2.4	12.5±2.2	0.216
BMI	35.6±8.8	36.9±9.4	34.2±7.8	0.103
Diabetes duration (years)	12.2±7.6	11.5±7.2	13.0±8.1	0.298
Baseline mean HbA1c	10.1±1.9	10.1±2.1	10.1±1.8	0.931

BMI, body mass index; HbA1c, hemoglobin A1c; HS, high school; TACM, technology-assisted case management.

TABLE 2. ANALYSES OF COVARIANCE FOR DIFFERENCES IN LEVELS OF HbA1c AT 6 MONTHS BETWEEN THE TREATMENT GROUPS, WITH BASELINE HbA1c AS COVARIATE

Parameter	Estimate	95% Confidence limits	P
Treatment			
Usual care	Ref	Ref	Ref
TACM	-0.99	-1.86	-0.13
Baseline HbA1c	0.56	0.33	0.79
			<0.001

Model 1- is the unadjusted ANCOVA. ANCOVA, analysis of covariance; Ref, reference group.

TACM and usual care using a random intercept and slope longitudinal model. The longitudinal model included the treatment group, assessment visit (time), and the interaction between treatment and assessment visit; a significant interaction would suggest that the trajectories of HbA1c levels over time were different between the two treatment groups. We chose between a random intercept and a random intercept and slope based on a likelihood-ratio test using maximum likelihood approximation. The above analyses were repeated for the PP population, defined as all participants who had complete outcome measurements at 6 months, to evaluate the impact of missing data on study results.

Role of funding source

The funding source of the study was the Department of Defense (Grant No. W81XWH-10-2-0057) and had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. Of note, the study was originally approved for 4 years of funding, but due to budgetary constraints, the funding agency decided to terminate funding after 3 years. As a result, the original sample size of 200 was not attained. After discussions between the funding source and the study team, including interim analyses and feasibility considerations in the timeline given the revised budget and constraints, it was decided to terminate the study at 113 subjects, reflecting the number of subjects that had been enrolled at the time the decision was made by the Department of Defense to terminate funding; this decision allowed at least 6 months of follow-up within the 3-year revised funding timeframe and adequate sample size to document differences in HbA1c.

TABLE 3. LONGITUDINAL MIXED EFFECTS ANALYSES FOR DIFFERENCES IN TRAJECTORIES OVER TIME IN LEVELS OF HbA1c BETWEEN THE TREATMENT GROUPS

Parameter	Estimate	95% Confidence limits	P
Treatment			
Usual care	Ref	Ref	Ref
TACM	-0.31	-1.03	0.41
Time	-0.03	-0.14	0.08
Time × treatment			
Time × usual care	Ref	Ref	Ref
Time × TACM	-0.16	-0.31	-0.01
			0.038

Model—is a longitudinal random intercept and slope model.

## Results

Between July 1, 2011 and April 30, 2013, the nurse case manager randomly assigned 113 participants (ITT population) to either the TACM intervention (54 [48%]) or usual care (59 [52%]). Figure 1 shows flow of patients through the study (CONSORT Diagram). There were 113 (100%) patients at baseline, 87 (77%) at 3 months, and 85 (75%) at 6 months that had complete HbA1c measurements. Among the 85 participants that had complete HbA1c measurements at 6 months (PP population), 41 (48%) were in TACM and 44 (52%) in the usual care group.

The nurse case manager achieved 100% protocol-specified fidelity, and all ratings exceeded 90% agreement for study assessments. There were 28 (25%) patients with missing HbA1c at 6-month follow-up. African Americans were 4.7 times more likely to complete the 6-month assessment visit compared to Whites ( $P=0.005$ ). The probability of missing HbA1c at 6 months was not significantly associated with the treatment group ( $P=0.868$ ) or any other demographic or baseline characteristics.

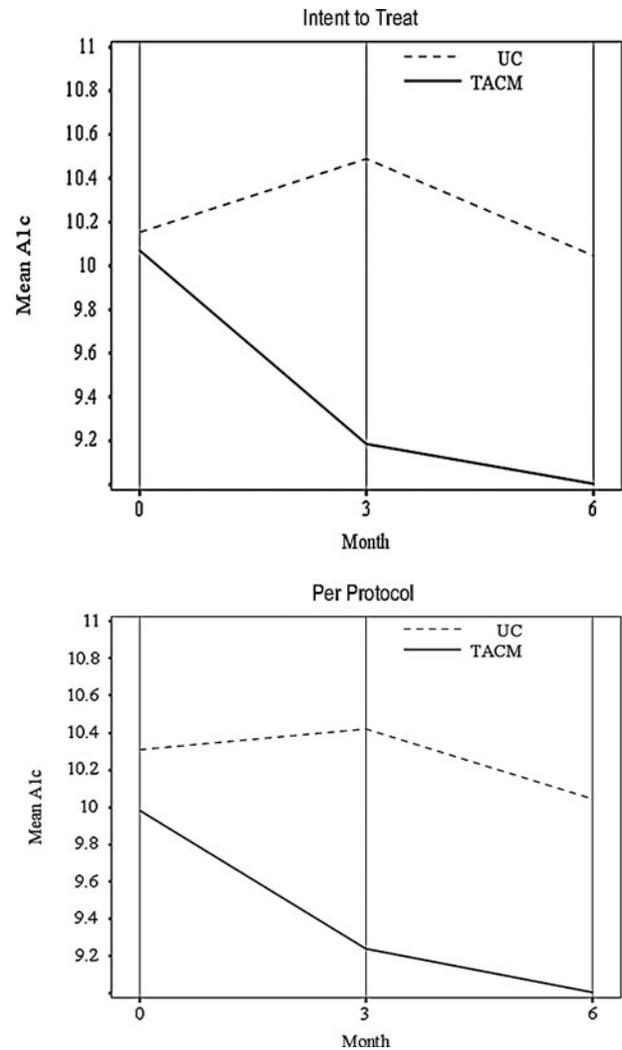
In Table 1, baseline characteristics for demographics and other variables of interest for the ITT population are presented. The majority of participants were women (81.4%), non-Hispanic Black (75.2%), not married (67.3%), with at least a high school diploma (79.6%). The mean age was 54 years old. There were no significant differences between groups in demographic characteristics.

Table 2 shows the ANCOVA on the ITT population, after imputation of missing data. At 6 months, the levels of HbA1c in the TACM group were 0.99 points significantly lower compared to the usual care group ( $P=0.024$ ). Levels of HbA1c at 6 months were significantly correlated with baseline levels of HbA1c where a unit change in baseline HbA1c resulted in a 0.56-unit change in HbA1c at 6 months ( $P$ -value  $<0.001$ ). Table 3 shows the longitudinal linear mixed effects analyses for the ITT population, after MIs. The interaction term suggests that the rate of decline in levels of HbA1c over time was significantly faster for TACM compared to the usual care group ( $-0.16$ ,  $P=0.038$ ). We repeated all analyses for the PP population, and the results were consistent with the ITT analyses, so we only report the ITT results in this article as per clinical trial guidelines.

Figure 2 shows a graph for the observed mean levels of HbA1c at each assessment visit. For the ITT population, the mean HbA1c levels were significantly different at 3 months ( $P=0.013$ ) and 6 months ( $P=0.041$ ). Results are similar for the PP population.

## Discussion

In this sample of adults with type 2 diabetes, participants in the TACM intervention group had significantly lower HbA1c levels at 6 months postrandomization compared to participants in the usual care group. Moreover, longitudinal mixed effects analyses suggested that the rate of decline in levels of HbA1c over time for TACM group participants was significantly faster compared to the usual care group participants. These findings suggest that a combined technology-assisted and nurse case management intervention in low income and rural patients with poorly controlled type 2 diabetes is efficacious compared to usual care.



**FIG. 2.** Mean levels of HbA1c over time by treatment group.

This study is inherently novel in that it optimized two strategies proven to improve glycemic control—nurse case management and telemonitoring—in a combined intervention to improve effective healthcare delivery in rural, underserved, and minority communities with type 2 diabetes. More importantly, it demonstrated that technology-assisted case management with medication titration by nurses under physician supervision is efficacious and safe and can be implemented in resource poor clinical settings. In addition, it is noteworthy to mention that this study also demonstrated the use of a solitary nurse case manager to manage a substantially large number of patients (i.e.,  $>100$ ), while continuing to provide quality care and maintain and monitor patient safety. Overall, this intervention provides a practical and sustainable system of diabetes management that can help low income and rural patients (regardless of geographic location) achieve and maintain goals within established guidelines. As the intervention utilized information technology, we believe this study also improved (1) communication between the patients and providers, (2) patient access to care, and (3) adherence to prescribed therapy as evidence in (1) daily uploads of blood glucose readings for real-time evaluation by the nurse,

(2) conversations with the nurse that increased access to the provider using the nurse as a mediator/moderator in the relationship, and (3) weekly or biweekly titration of medications that increased adherence to self-management, respectively.

Our findings are supported by evidence from previous studies evaluating the use and safety of nurse case management on healthcare outcomes in patients with diabetes. In a review to determine the effectiveness of nurse case managers on improving glucose control in a large sample of high-risk Veterans, nurse case managers helped the patients achieve a significant reduction ( $\sim 2\%$ ) in HbA1c levels.<sup>25</sup> This improvement was sustained over 2 years of follow-up indicating success in long-term management of diabetes using nurse case management.<sup>27</sup> Similar to the protocol and processes of our study, nurse-delivered care driven by protocol-based medication titration resulted in a significant reduction in HbA1c ( $P < 0.001$ ; 95% confidence interval [CI], 1.68 to 2.24) in a new model of diabetes chronic disease management.<sup>26</sup> These findings demonstrated the success, safety, and efficacy of nurse-managed diabetes care. Furthermore, in a review by Watts and Lucatorto<sup>27</sup> to assess the use and safety of nurse case managers in chronic disease management for diabetes, safety concerns such as hypoglycemia, emergency room visits, hospitalizations, and other adverse events were not an issue when using nurses for diabetes care management.

There is continuously growing evidence on the usefulness and effectiveness of technological advances in healthcare; our findings are supported by this evidence. In a study to assess the effectiveness, acceptability, and costs of telemedicine as an alternative or complement to usual care, Flodgren et al. found that diabetes was among clinical conditions assessed using telemonitoring and that telemonitoring provided remote monitoring or real-time access for monitoring clinical conditions.<sup>21</sup> More importantly, in studies recruiting patients with diabetes, they found significantly lower HbA1c levels (mean difference of  $-0.31$ ;  $P < 0.001$ ) in the individuals randomized to telemonitoring compared to those receiving usual care.<sup>21</sup> Overall, they concluded that telemonitoring was useful toward improving blood glucose in patients with diabetes.<sup>21</sup> Similarly, in a review to assess potential benefits of home telehealth compared to usual care in patients with diabetes, Polisena et al. found that home telehealth positively impacted glycemic control, demonstrated by a significantly lower mean difference of  $-0.21$  (95% CI,  $-0.35$  to  $-0.08$ ) in HbA1c between telehealth users and those receiving usual care.<sup>28</sup>

While this study had a significant effect of reducing HbA1c and improving glycemic control in the TACM intervention group, there are a couple of challenges and limitations worth mentioning. First, as this study was projected to last 4 years, a priori hypotheses were generated based on a carefully and rigorously calculated sample size ( $n = 200$ ). Due to a discontinuation of funding in year 3, study processes and procedures were adjusted resulting in a smaller sample size than initially calculated ( $n = 113$ ). It is possible that larger effect sizes may have been found had the original number of participants been recruited to participate in the study; however, this evidence remains unknown. It is possible that a larger sample size may have resulted in different results (either larger or smaller), so the true effect size would need to be evaluated in future studies. Second, as with the

introduction of and advances in technology,  $\sim 10\%$  of the patients experienced initial limitations with uploading blood glucose readings using the telehealth device. As a participant in the study, the patients were asked to upload their blood sugar measurements daily, however, because of early issues with learning to use the device and transmit data, daily uploads were not possible for some of patients. As such, the nurse case manager made home visits to set up the devices properly and troubleshoot problems encountered with the devices for some of the older patients, those with physical impairments and those with connectivity issues. However, after the first few weeks, these challenges were resolved, so it will be important to build in a lead in time for future studies that use novel technologies. Third, we did not control for attention in the intervention group; therefore, it is reasonable to suggest that while diabetes education and skills training were not directly provided to the patients in the control group, support of any kind from the nurse case manager may have influenced behaviors that resulted in improved glycemic control.

Overall, these findings suggest that a combined technology-assisted and nurse case management intervention in low income and rural patients with poorly controlled type 2 diabetes is efficacious compared to usual care. The findings of this study have the potential to enhance efficiency of care, speed the implementation of effective treatment plans, and decrease the morbidity and mortality associated with type 2 diabetes. Ultimately, it has the potential to reduce overall healthcare costs and disparate care associated with diabetes management.

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### Author's Contribution

L.E.E. obtained funding for the study. R.G.K. and D.C.V. performed the statistical analyses. J.S.W., D.C.V., and L.E.E. drafted the article. L.E.E., J.S.W., D.C.V., R.G.K., and J.F. reviewed and edited the final draft. L.E.E. and R.G.K. are the guarantors of the work.

### Author Disclosure Statement

No competing financial interests exist.

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