

Effect of a Comprehensive Telehealth Intervention vs Telemonitoring and Care Coordination in Patients With Persistently Poor Type 2 Diabetes Control A Randomized Clinical Trial

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IMPORTANCE Persistently poorly controlled type 2 diabetes (PPDM) is common and causes poor outcomes. Comprehensive telehealth interventions could help address PPDM, but effectiveness is uncertain, and barriers impede use in clinical practice.

OBJECTIVE To address evidence gaps preventing use of comprehensive telehealth for PPDM by comparing a practical, comprehensive telehealth intervention to a simpler telehealth approach.

DESIGN, SETTING, AND PARTICIPANTS This active-comparator, parallel-arm, randomized clinical trial was conducted in 2 Veterans Affairs health care systems. From December 2018 to January 2020, 1128 outpatients with PPDM were assessed for eligibility and 200 were randomized; PPDM was defined as maintenance of hemoglobin A_{1c} (HbA_{1c}) level of 8.5% or higher for 1 year or longer despite engagement with clinic-based primary care and/or diabetes specialty care. Data analyses were preformed between March 2021 and May 2022.

INTERVENTIONS Each 12-month intervention was nurse-delivered and used only clinical staffing/resources. The comprehensive telehealth group (n = 101) received telemonitoring, self-management support, diet/activity support, medication management, and depression support. Patients assigned to the simpler intervention (n = 99) received telemonitoring and care coordination.

MAIN OUTCOMES AND MEASURES Primary (HbA_{1c}) and secondary outcomes (diabetes distress, diabetes self-care, self-efficacy, body mass index, depression symptoms) were analyzed over 12 months using intent-to-treat linear mixed longitudinal models. Sensitivity analyses with multiple imputation and inclusion of clinical data examined the impact of missing HbA_{1c} measurements. Adverse events and intervention costs were examined.

RESULTS The population (n = 200) had a mean (SD) age of 57.8 (8.2) years; 45 (22.5%) were women, 144 (72.0%) were of Black race, and 11 (5.5%) were of Hispanic/Latinx ethnicity. From baseline to 12 months, HbA_{1c} change was −1.59% (10.17% to 8.58%) in the comprehensive telehealth group and −0.98% (10.17% to 9.19%) in the telemonitoring/care coordination group, for an estimated mean difference of −0.61% (95% CI, −1.12% to −0.11%; P = .02). Sensitivity analyses showed similar results. At 12 months, patients receiving comprehensive telehealth had significantly greater improvements in diabetes distress, diabetes self-care, and self-efficacy; no differences in body mass index or depression were seen. Adverse events were similar between groups. Comprehensive telehealth cost an additional \$1519 per patient per year to deliver.

CONCLUSIONS AND RELEVANCE This randomized clinical trial found that compared with telemonitoring/care coordination, comprehensive telehealth improved multiple outcomes in patients with PPDM at a reasonable additional cost. This study supports consideration of comprehensive telehealth implementation for PPDM in systems with appropriate infrastructure and may enhance the value of telehealth during the COVID-19 pandemic and beyond.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: [NCT03520413](https://clinicaltrials.gov/ct2/show/study/NCT03520413)

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Patients with persistently poor type 2 diabetes (T2D) control disproportionately experience negative outcomes.¹⁻³ We have defined persistently poorly controlled diabetes (PPDM) as maintenance of hemoglobin A_{1c} (HbA_{1c}) level of 8.5% or greater for more than 1 year despite receiving clinic-based diabetes care; 10% to 15% of all patients with T2D meet PPDM criteria.^{4,5} Given their high risk for complications and costs,¹⁻³ patients with PPDM represent a compelling population for care delivery redesign.

Drivers of PPDM, including unavailable blood glucose data, medication nonadherence, suboptimal diet/activity, complex medications, and depression,⁶⁻¹² can be difficult to address in the clinic setting.^{13,14} By facilitating contact outside of clinic, telehealth could improve outcomes in PPDM. Telehealth strategies targeting individual factors underlying poor T2D control reduce HbA_{1c} level vs clinic-based care by 0.3% to 0.6%.¹⁵⁻¹⁹ Although such HbA_{1c} changes may not suffice for patients with PPDM, combining multiple strategies into comprehensive telehealth interventions could produce greater improvement. However, multicomponent T2D interventions have achieved variable results.²⁰⁻²⁵

Beyond this uncertain effectiveness, other barriers have hindered implementation of comprehensive telehealth for PPDM in practice. Implementation barriers include intervention designs reliant on research-funded staff and resources, insufficient electronic health record (EHR) integration of patient data, and uncertain reimbursement.²⁶⁻²⁹ Before comprehensive telehealth can become a real-world solution for PPDM, approaches are needed that are unambiguously effective and also explicitly designed for feasible implementation. The upsurge in telehealth use during the COVID-19 pandemic has only strengthened the case for considering comprehensive telehealth as a means to address PPDM.³⁰

We sought to address barriers to practical use of comprehensive telehealth for PPDM by evaluating a comprehensive telehealth intervention in a randomized clinical trial (RCT). This intervention combined 5 strategies targeting contributors to PPDM: telemonitoring, self-management support, diet/activity support, medication management, and depression support. To facilitate eventual implementation, we explicitly designed the intervention for delivery by clinical Veterans Health Administration (VHA) Home Telehealth (HT) nurses using existing clinical resources.

Methods

The protocol for this active-comparator, parallel-arm RCT (NCT03520413) has been published⁵ and appears in Supplement 1. We compared a practical, comprehensive telehealth intervention with a simpler telehealth approach, consisting of telemonitoring and care coordination, which is already available in VHA practice for T2D. A usual-care comparator was deemed inappropriate because clinic-based care is by definition insufficient for PPDM.³¹

This RCT was conducted at 2 VHA sites (Durham, North Carolina, and Richmond, Virginia). Institutional review boards at both sites approved the study. This study followed the Con-

Key Points

Question Compared with a simpler telehealth approach (telemonitoring and care coordination), can a practical, comprehensive telehealth intervention improve outcomes among patients whose type 2 diabetes remains persistently poorly controlled despite clinic-based care?

Findings In this randomized clinical trial of 200 adults with persistently poorly controlled type 2 diabetes, hemoglobin A_{1c} level improved by 1.59% at 12 months among those randomized to receive the comprehensive telehealth intervention, compared with 0.98% for the telemonitoring/care coordination group.

Meaning A comprehensive telehealth intervention improved outcomes in persistently poorly controlled type 2 diabetes compared with a simpler telehealth intervention; because it was explicitly designed for feasible use in clinical practice, this approach may warrant implementation in systems that need to improve diabetes control in which the requisite infrastructure is available.

solidated Standards of Reporting Trials (CONSORT) reporting guideline.

Population

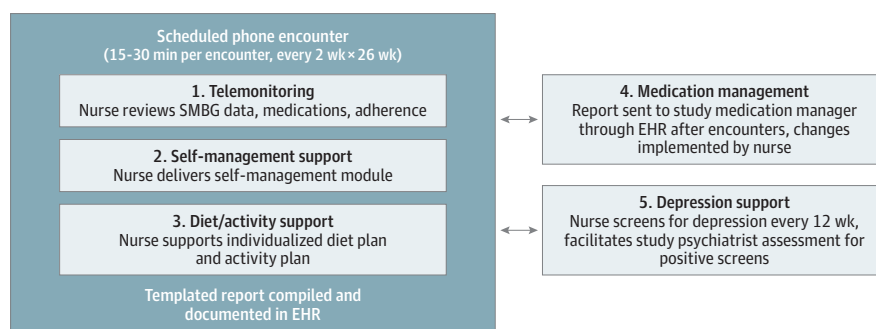
We recruited patients with PPDM, defined as the following: diagnosed T2D (*International Statistical Classification of Diseases and Related Health Problems, Tenth Revision* E11); 2 or more HbA_{1c} values of 8.5% or greater during the prior year with none less than 8.5%; and at least 1 appointment during the prior year with a primary care clinician or diabetes specialist (endocrinologist or other diabetes clinician). Exclusion criteria included the following: refusal to enroll in VHA HT (because both study interventions were delivered by HT nurses); factors making HbA_{1c} reduction potentially inadvisable (age >70 years, metastatic cancer/life expectancy <5 years, recent cardiovascular disease complications, or prior hypoglycemic seizure/coma); lack of telephone access; dementia, psychosis, or substance use disorder; pregnancy; receiving dialysis or skilled nursing care; insulin pump use; or continuous glucose monitor use (unless also willing to submit self-monitored blood glucose [SMBG] data per HT protocol).

Race was determined by self-report and categorized as Asian, American Indian or Alaska Native, Black or African American, Native Hawaiian or Other Pacific Islander, White, other, or unknown. Because of low numbers in the other categories, race was ultimately presented as Black or African American, White, or other race. Self-reported ethnicity was assessed using a single question: "Are you of Latino/a or Hispanic origin or descent?" Race and ethnicity data were collected to facilitate generalizability assessment and to determine whether intervention effectiveness varied by these factors.

Recruitment and Enrollment

After EHR screening, a research assistant mailed opt-out letters to potential participants, then conducted phone screening. Eligible participants provided informed consent and underwent in-person baseline assessment; consented patients with a baseline HbA_{1c} level of less than 8.5% were excluded

Figure 1. Comprehensive Telehealth Intervention Design



Adapted with permission from Kobe et al.⁵ EHR indicates electronic health record; SMBG, self-monitored blood glucose.

before randomization. Given the high proportion of men in the VHA population, we oversampled women, aiming to achieve greater than 20% in the randomized population.

Randomization and Blinding

Randomization was stratified with blocks of 2; stratification variables were site, prior VHA HT use, and preenrollment diabetes specialty care (endocrinologist or other diabetes clinician). The computer-generated randomization sequence was accessible only to study statisticians. Patients received randomization assignments by phone from the project coordinator within 1 week of consent. Because participants received information about both interventions during consent, they were not blinded to randomization arm. Research assistants collecting outcome data were blinded to participant randomization status.

Interventions

Both 12-month interventions were delivered by clinical HT nurses rather than research staff. Although experienced with telehealth-based disease care, these nurses had no specialized diabetes training. Individual nurses delivered only 1 study intervention, with no crossover. Each intervention was delivered by 1 nurse in Durham, while in Richmond, 2 nurses delivered comprehensive telehealth and 5 delivered telemonitoring/care coordination.

Following randomization, all participants enrolled in VHA HT. Patients enrolled in HT used a telehealth device (Medtronic), blood glucose meter (Abbott), and connector cable; once connected to the blood glucose meter, the telehealth device automatically transmitted SMBG data to HT. After HT enrollment, participants began their assigned intervention; both groups also continued care with existing clinicians. Patients' HbA_{1c} goals were individualized per American Diabetes Association guidelines.³²

Comprehensive Telehealth Intervention

This intervention comprised 5 nurse-delivered components (Figure 1)⁵: telemonitoring, self-management support, diet/activity support (together with a study dietitian), medication management (together with a study medication manager), and depression support (together with a study psychiatrist). The

study dietitian, medication managers, and psychiatrists were clinicians, not research staff. Intervention nurses completed a single training session and received a manual. Nurses delivered the intervention to participants during 26 every-2-week telephone encounters, which the nurses scheduled directly with participants; nurses could additionally be reached for acute issues. Clinical information was tracked using templated EHR notes.

For the telemonitoring component, participants transmitted SMBG data up to 4 times daily based on their medication regimens but could monitor less frequently per nurse discretion. During each of the 26 scheduled encounters, the nurse reviewed SMBG data, reconciled medications, and assessed self-reported medication adherence.

For the self-management support component, intervention nurses delivered module-based self-management education during 16 of the 26 scheduled encounters. Each module covered a unique topic addressing knowledge and/or self-efficacy.⁵

For the diet/activity support component, a dietitian called participants with a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) of 25 or greater to develop an individualized diet plan postenrollment. Plans were tailored to patient preferences and targeted to greater than 5% weight loss via a deficit of 500 to 750 calories per day.³³ Patients were also encouraged to maintain 150 minutes or more of moderate to vigorous activity weekly.³⁴ During each of the 26 scheduled encounters, the nurse reviewed progress. An additional dietitian phone follow-up could be arranged for patients not meeting goals.

For the medication management component, each site used 2 to 3 diabetes specialists (physicians, clinical pharmacists, or nurse practitioners). After each of the 26 scheduled encounters, the intervention nurse forwarded an EHR-based summary note to the medication manager. The medication manager considered treatment changes with guidance from a medication protocol, which targeted a fasting glucose level of 90 to 150 mg/dL and preprandial glucose level of 140 to 180 mg/dL (tailoring permitted based on HbA_{1c} goal/hypoglycemia; to convert glucose level to mmol/L, multiply by 0.0555). The medication manager conveyed recommendations via an EHR note addendum, which the nurse implemented; medi-

cation managers did not routinely contact participants. Primary clinicians were alerted to changes via the EHR.

For the depression support component, participants with a Personal Health Questionnaire-8 (PHQ-8) score of 10 or higher at baseline or subsequent screening entered the depression protocol, which was supported by 1 psychiatrist at each site and provided pharmacologic and nonpharmacologic options.³⁵ All patients receiving depression support had PHQ-8 follow-up every 8 weeks, with treatment changes as needed.

Telemonitoring/Care Coordination Intervention

Participants transmitted SMBG data and received automated self-management information daily by phone. Participants received nurse calls for alert SMBG values and could reach nurses as needed for acute issues but did not complete scheduled encounter calls. Participants also received care coordination, including communication about upcoming appointments, notification of primary clinicians regarding acute needs, and preappointment compilation of SMBG data for review by primary clinicians. Diabetes medication management was not formally integrated into this intervention; instead, medication adjustments were at the discretion of existing clinicians during or outside of scheduled encounters. Of note, because telemonitoring/care coordination is considered routine HT practice, no training was required for nurses delivering this intervention.

Outcomes

Outcome assessments were performed by blinded research assistants at 3-month intervals for 12 months. Full assessments were completed at 0, 6, and 12 months, with additional HbA_{1c}-only assessments at 3 and 9 months.

The primary outcome was HbA_{1c} level. Secondary outcomes were diabetes distress,³⁶ diabetes self-care,³⁷ self-efficacy,³⁸ BMI, and depression symptoms.³⁹ Adverse events were assessed by structured self-report⁴⁰; incidence of blood glucose level less than 70 mg/dL was also examined using SMBG data transmitted to HT in both arms.

Intervention Costs

Intervention costs were examined in both arms. Labor costs included all intervention nurse, dietitian, medication manager, and psychiatrist time spent delivering the intervention; capital costs included HT equipment, telephone service costs, overhead, and supplies.

Fidelity Assessment

Fidelity assessment for the comprehensive telehealth intervention included nurse tracking of encounters and time using online software. The principal investigator and project coordinator conducted periodic shadowing of nurses and biannual case review meetings with the medication managers.⁵ Updated medications were tracked at outcome visits.

Influence of COVID-19 Pandemic on Outcome Ascertainment

In March 2020, VHA announced a pandemic-related restriction on in-person research interactions. Survey data collec-

tion continued by phone when possible, but study measurement of HbA_{1c} level and BMI was interrupted. In May 2020, we received permission to resume collection of HbA_{1c} level given its importance to diabetes management; however, BMI could not be measured after March 2020, which affected the 12-month time point for 169 participants. Despite the pandemic, intervention delivery continued uninterrupted at both sites.

Statistical Analyses

Sample Size

Per previous data,³¹ we used an α level of .05, 80% power, 20% dropout, within-patient correlation 0.55, SD 1.6, and baseline HbA_{1c} level of 10.3% to estimate that 100 participants per arm would detect a clinically significant HbA_{1c} difference of 0.6% at 12 months.⁴¹ Power estimates were derived by generating 1000 simulated data sets with these assumptions and fitting linear mixed models to assess the effect difference at 12 months.

Analytic Approach

All analyses were intention-to-treat and performed using SAS, version 9.4 (SAS Institute).⁴² Linear mixed longitudinal models were used for all primary and secondary outcomes.⁴³ The primary outcome model included fixed effects for linear, quadratic and cubic time, time-by-arm interaction terms, and randomization stratification variables, and random effects for intercept and linear time (see eMethods in Supplement 2). The covariance structure was determined using Akaike information criteria.⁴⁴ Our primary inference was on the estimated between-arm 12-month HbA_{1c} difference. As a post hoc sensitivity analysis, we included baseline covariates with between-arm differences in the primary model. Also, to explore a dose-response effect of the comprehensive telehealth intervention, we conducted a descriptive post hoc analysis examining HbA_{1c} change among participants completing more than 20 vs 20 or fewer encounters.

For secondary outcomes, fixed effects included dummy-coded time effects for each time point and time-by-arm interaction terms. Given the pandemic's hindrance of BMI ascertainment, BMI was analyzed only at 0 and 6 months. To account for within-participant repeated measures, we fit an unstructured covariance. We descriptively analyzed intervention engagement (encounter completion, SMBG transmission), adverse events, and costs.

Missing Data

Our analyses implicitly accommodated missingness when related to prior outcome data or other baseline model covariates defined as missing at random (MAR). As a sensitivity analysis for the primary model, we also multiplied imputed missing HbA_{1c} data using a Markov chain Monte Carlo algorithm incorporating additional variables to strengthen the MAR assumption (see eMethods in Supplement 2). With the pandemic's influence on outcome ascertainment, we conducted another sensitivity analysis fitting our primary model with inclusion of additional clinical HbA_{1c} measurements obtained from the EHR.

Data Monitoring Committee

Our data monitoring committee comprised the study statisticians (A.S.J. and C.J.C.) and 3 independent experts. This committee met at 6-month intervals during the study and examined recruitment, retention, randomization, adverse events, and outcomes.

Results

Participants, Retention, and Fidelity

Participants were enrolled from December 2018 through January 2020; participant contact concluded in January 2021. Of 1128 individuals assessed, 257 were consented, and 200 were randomized (Figure 2); most of those consented but not randomized were excluded for baseline HbA_{1c} level of less than 8.5%. Randomized participants were similar to those declining participation (eTable 1 in Supplement 2). Of those randomized, 101 were allocated to comprehensive telehealth and 99 to telemonitoring/care coordination; all were analyzed in their randomized group, and there was no between-arm crossover.

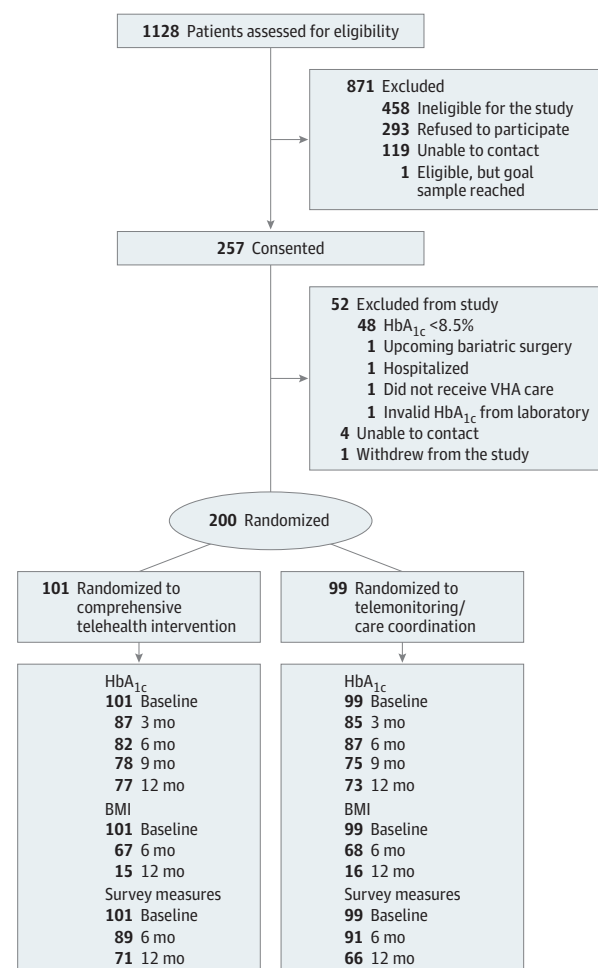
Per Table 1, participants had baseline mean (SD) age of 57.8 (8.2) years, HbA_{1c} level of 10.2% (1.3%), and BMI of 34.8 (6.7). A total of 45 (22.5%) participants were women; 144 (72.0%) were Black, 11 (5.5%) were Hispanic/Latinx, 42 (21.0%) were White, and 14 (7.0%) were of other race. Prior to enrollment, 136 (68.0%) participants had received diabetes specialty care, and 12 (6.0%) had received HT care. Baseline characteristics were generally balanced across arms; moderate between-arm imbalances were noted in race, medication use, BMI, and social support.

Overall, 150 of 200 (75%) participants completed the 12-month assessment for HbA_{1c} level, and 137 (68.5%) for survey-based outcomes (Figure 2). Participants in the comprehensive telehealth arm completed an average of 19.6 of 26 possible encounters; 33 participants completed 20 or fewer encounters, and 14 completed 10 or fewer. Mean (SD) encounter time was 17.0 (11.2) minutes. Telemonitoring, self-management support, diet/activity support, and medication management were delivered during all completed comprehensive telehealth encounters; 30 of 101 (29.7%) participants initiated depression support based on elevated PHQ-8 score at baseline, and 23 of 90 (25.6%) at 6 months. Because the telemonitoring/care coordination intervention did not involve scheduled encounters, encounter metrics were not tracked. Both groups experienced changes in medication use during the study (eTable 2 in Supplement 2); descriptively, the comprehensive telehealth group had greater increases in use of glucagon-like peptide-1 receptor agonists (+15% vs +8%) and dipeptidyl peptidase-4 inhibitors (+5% vs +1%) from baseline to 12 months.

Primary Outcome

Between baseline and 12 months, estimated HbA_{1c} change was −1.59% (10.17% to 8.58%) in the comprehensive telehealth group and −0.98% (10.17% to 9.19%) in the telemonitoring/care coordination group; the estimated difference of −0.61% (95% CI, −1.12% to −0.11%; $P = .02$) favored comprehensive tele-

Figure 2. Participant Flow



BMI indicates body mass index, calculated as weight in kilograms divided by height in meters squared; HbA_{1c}, hemoglobin A_{1c}; VHA, Veterans Health Administration.

health (Table 2, Figure 3). Three-way interactions between intervention arm, time, and key stratification variables were not statistically significant, indicating no evidence for differential HbA_{1c} effects over time based on preenrollment diabetes specialty care or study site.

Similar results were found on sensitivity analyses with MAR imputation using multiply imputed data sets (mean 12-month difference, −0.63%; 95% CI, −0.95% to −0.35%; $P = .03$) and inclusion of additional clinical HbA_{1c} measures from the study period ($n = 191$ from 62 comprehensive telehealth and 63 telemonitoring/care coordination participants; mean 12-month difference, −0.50%; 95% CI, −0.99% to −0.01%; $P = .04$). Findings with baseline covariate adjustment (race; insulin, metformin, sulfonylurea, sodium-glucose cotransporter-2 inhibitor use; BMI; social support) were also similar (mean 12-month difference, −0.66%; 95% CI, −1.17% to −0.14%; $P = .01$).

On exploratory descriptive analyses (eTable 3 in Supplement 2), comprehensive telehealth patients who completed

Table 1. Baseline Characteristics, Overall and Stratified by Study Arm

Baseline characteristics	No. (%)		
	Overall (n = 200)	Comprehensive telehealth (n = 101)	Telemonitoring/care coordination (n = 99)
Demographic characteristics			
Age, mean (SD), y	57.8 (8.2)	57.7 (8.3)	57.8 (8.0)
Sex			
Female	45 (22.5)	24 (23.8)	21 (21.2)
Male	155 (77.5)	77 (76.2)	78 (78.8)
Race			
Black or African American	144 (72.0)	68 (67.3)	76 (76.8)
White	42 (21.0)	25 (24.8)	17 (17.2)
Other race ^a	14 (7.0)	8 (7.9)	6 (6.0)
Hispanic/Latino ethnicity ^b	11 (5.5)	6 (5.9)	5 (5.1)
Did not graduate high school	57 (28.5)	29 (28.7)	28 (28.3)
Currently married	91 (45.5)	45 (46.5)	46 (45.5)
Social support ^{c,d}	191 (95.5)	98 (97.0)	93 (93.9)
Employed (full/part-time/self)	90 (45.0)	48 (47.5)	42 (42.4)
Study site			
Durham	115 (57.5)	57 (56.4)	58 (58.6)
Richmond	85 (42.5)	44 (43.6)	41 (41.4)
Years with diabetes, mean (SD)	12.1 (7.7)	12.1 (8.0)	12.0 (7.5)
Prior diabetes specialty care	136 (68.0)	69 (68.3)	67 (67.7)
Prior Home Telehealth enrollment	12 (6.0)	6 (5.9)	6 (6.1)
Clinical measures			
Baseline HbA _{1c} , mean (SD), %	10.2 (1.3)	10.1 (1.2)	10.2 (1.4)
BMI, mean (SD)	34.8 (6.7)	34.5 (6.4)	35.2 (7.0)
Hypertension	166 (83.0)	81 (80.2)	85 (85.9)
Hypertlipidemia ^d	171 (85.5)	84 (83.2)	87 (87.9)
Tobacco use in past 6 mo	30 (25.4)	16 (30.2)	14 (21.5)
Metformin	160 (80.0)	78 (77.2)	82 (82.8)
Sulfonylurea	83 (41.5)	35 (34.7)	48 (48.9)
Thiazolidinedione	14 (7.0)	7 (6.9)	7 (7.1)
SGLT-2 inhibitor	22 (11.0)	15 (14.9)	7 (7.1)
GLP-1 receptor agonist	25 (12.5)	11 (10.9)	14 (14.1)
DPP-4 inhibitor	4 (2.0)	0	4 (4.0)
Insulin use	142 (71.0)	78 (77.2)	64 (64.6)
Psychosocial measures			
Diabetes distress (DDS), mean (SD)	1.9 (0.8)	1.9 (0.7)	1.9 (0.9)
Diabetes self-care (DSMQ), mean (SD)	6.7 (1.6)	6.9 (1.5)	6.5 (1.7)
Self-efficacy (PCS), mean (SD)	5.2 (1.5)	5.2 (1.5)	5.2 (1.4)
Depression (PHQ-8) score, mean (SD) ^e	7.3 (5.7)	7.0 (5.2)	7.6 (6.1)

Abbreviations: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; DDS, Diabetes Distress Scale; DPP-4, dipeptidyl peptidase-4; DSMQ, Diabetes Self-Management Questionnaire; GLP-1, glucagon-like peptide-1; HbA_{1c}, hemoglobin A_{1c}; PCS, Perceived Competence Scale; PHQ-8, Patient Health Questionnaire-8; SGLT-2, sodium-glucose cotransporter-2.

^a Because of low numbers in the Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, other, and unknown categories, these were combined into a single category, "other race."

^b One patient in the telemonitoring/care coordination group responded "Don't know" to the Hispanic/Latino ethnicity question.

^c Social support was assessed by asking, "Do you have someone you feel close to, someone you can trust and confide in?"

^d One patient in the comprehensive telehealth group responded "Don't know" to having high cholesterol and to having social support.

^e One patient in the comprehensive telehealth group and 1 patient in the telemonitoring/care coordination group were missing the PHQ-8 score.

more than 20 encounters (n = 68) experienced greater HbA_{1c} reduction (1.84%) than those who completed 20 or fewer (n = 33, 0.79%).

Secondary Outcomes

Per Table 2, the comprehensive telehealth group had a greater improvement than the telemonitoring/care coordination group at 12 months for diabetes distress (mean difference, −0.25; 95% CI, −0.42 to −0.07), diabetes self-care (mean difference, 0.51; 95% CI, 0.25 to 0.78), and self-efficacy (mean difference, 0.39; 95% CI, 0.07 to 0.71). There were no statistically significant be-

tween-group differences in depressive symptoms (12 months) or BMI (6 months).

Adverse Events

Adverse events were similar between arms. Comprehensive telehealth participants had 26 serious events (16 hospitalizations), 3 possibly study-related (episodes of ketoacidosis, hyperglycemia, and possible medication-related urinary infection). In the telemonitoring/care coordination group, there were 19 serious events (17 hospitalizations, 1 death), none deemed study-related. Among the 97 comprehensive telehealth par-

Table 2. Estimated Outcome Means and Mean Differences for Comprehensive Telehealth (n = 101) and Telemonitoring/Care Coordination (n = 99) Arms by Time Point^a

Outcome	Estimated mean		Estimated mean difference (95% CI)	P value
	Comprehensive telehealth	Telemonitoring/care coordination		
HbA_{1c}, %				
Baseline	10.17	10.17	NA	NA
3 mo	8.90	9.18	-0.29 (-0.48 to -0.09)	NA
6 mo	8.54	9.03	-0.48 (-0.78 to -0.18)	NA
9 mo	8.61	9.20	-0.60 (-0.96 to -0.22)	NA
12 mo	8.58	9.19	-0.61 (-1.12 to -0.11)	.02
Diabetes distress (DDS)^b				
Baseline	1.93	1.93	NA	NA
6 mo	1.53	1.57	-0.04 (-0.18 to 0.09)	NA
12 mo	1.43	1.67	-0.25 (-0.42 to -0.07)	.007
Diabetes self-care (DSMQ)^c				
Baseline	6.67	6.67	NA	NA
6 mo	8.15	7.92	0.22 (-0.07 to 0.51)	NA
12 mo	8.34	7.83	0.51 (0.25 to 0.78)	<.001
Self-efficacy (PCS)^d				
Baseline	5.20	5.20	NA	NA
6 mo	6.09	5.84	0.24 (-0.06 to 0.54)	NA
12 mo	6.31	5.92	0.39 (0.07 to 0.71)	.02
BMI				
Baseline	34.81	34.81	NA	NA
6 mo	35.05	34.86	0.19 (-0.24 to 0.62)	.39
Depression symptoms (PHQ-8)^e				
Baseline	7.32	7.32	NA	NA
6 mo	6.54	6.06	0.48 (-0.72 to 1.69)	NA
12 mo	4.64	5.80	-1.16 (-2.53 to 0.21)	.10

Abbreviations: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; DDS, Diabetes Distress Scale; DSMQ, Diabetes Self-Management Questionnaire; HbA_{1c}, hemoglobin A_{1c}; NA, not applicable; PCS, Perceived Competence Scale; PHQ-8, Patient Health Questionnaire-8.

^a Missing data by time point for the comprehensive telehealth group were as follows: HbA_{1c}: 3 months n = 14, 6 months n = 19, 9 months n = 23, 12 months n = 22; survey measures: 6 months n = 12, 12 months n = 30; BMI: 6 months n = 34. Missing data by time point for the telemonitoring/care coordination group were as follows: HbA_{1c}: 3 months n = 14, 6 months n = 12, 9 months n = 24, 12 months n = 26; survey measures: 6 months n = 10, 12 months n = 35; BMI: 6 months n = 33. No data points were missing at baseline.

^b A lower score on the DDS indicates lower levels of diabetes distress, so is preferred.

^c A higher score on the DSMQ indicates better diabetes self-care, so is preferred.

^d A higher score on the PCS indicates higher self-efficacy, so is preferred.

^e A lower score on the PHQ-8 indicates fewer depressive symptoms, so is preferred.

ticipants with available SMBG data, 70 (72.1%) reported 1 or more SMBG values less than 70 mg/dL over 12 months, with a per-patient mean (SD) of 7.3 (9.8). Among the 89 telemonitoring/care coordination participants with available SMBG data, 61 (68.5%) reported 1 or more SMBG values less than 70 mg/dL over 12 months, with a per-patient mean (SD) of 6.9 (11.1).

Intervention Costs

Per-patient intervention costs were \$2465 for comprehensive telehealth and \$946 for telemonitoring/care coordination, for a between-arm difference of \$1519 over 12 months.

Discussion

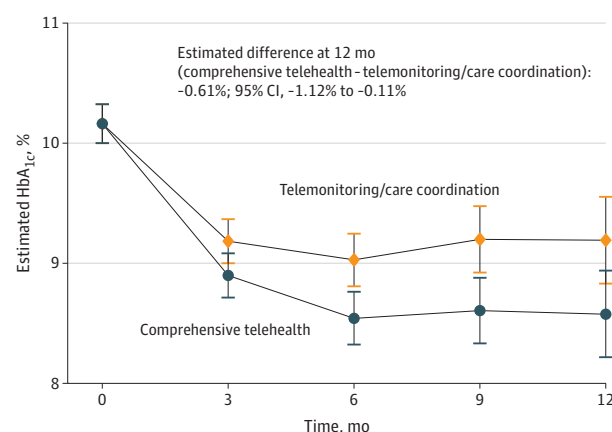
We sought to promote practical use of telehealth for PPDM by comparing 2 approaches designed for feasible clinical implementation: a comprehensive telehealth intervention and telemonitoring/care coordination. While both approaches improved HbA_{1c} level, the comprehensive telehealth intervention produced a greater 12-month improvement in HbA_{1c} level and multiple secondary outcomes, without excess hypoglycemia.

These findings demonstrate that practically designed telehealth can be effective for patients whose T2D remains per-

sistently poorly controlled despite clinic-based care. Moreover, combining telehealth strategies to target multiple barriers to improvement lowers HbA_{1c} level more than simpler approaches like telemonitoring/care coordination. Given our active-comparator design, we cannot exclude that the within-arm HbA_{1c} effects (-1.59% for comprehensive telehealth and -0.98% for telemonitoring/care coordination) may partly reflect regression to the mean; for example, the -0.98% HbA_{1c} improvement with telemonitoring/care coordination exceeds the effect reported for telemonitoring in systematic reviews (-0.4% to 0.5% vs usual care).^{15,45-47} However, the relative HbA_{1c} benefit seen with comprehensive telehealth in this study (-0.61%) was not subject to regression to the mean. Importantly, the HbA_{1c} reduction with comprehensive telehealth was durably retained through 12 months.

While the comprehensive telehealth intervention was more expensive (additional \$1519 over 12 months), this incremental cost is less than most branded glucose-lowering medications, and the comprehensive approach came with added benefits for diabetes distress, self-care, and self-efficacy. Given the high complication rates characteristic of PPDM and the long-term cost benefits of HbA_{1c} reduction,^{1,2} implementing comprehensive telehealth in practice may represent an appropriate investment for health care systems in which the requisite infrastructure is or can be made available.

Figure 3. Estimated Trajectories by Arm for Hemoglobin A_{1c} (HbA_{1c}) Level, From Linear Mixed Models



Error bars indicate 95% CIs.

When we developed this study, our focus was on leveraging the VHA's telehealth infrastructure to generate solutions for PPDM. Since then, the COVID-19 pandemic has driven a dramatic upsurge in telehealth use worldwide. Currently, *telehealth*, as used by most systems, implies intermittent video or phone appointments,^{30,48-50} with limited interim patient-clinician contact or transfer of patient-generated data into the EHR—in essence, “clinic-like” care, only delivered remotely. Just as clinic-based care does not fully address the factors underlying PPDM, “clinic-like” telehealth is also likely inadequate. There has always been a sound argument for using comprehensive telehealth when clinic-based chronic disease care falls short; now that telehealth has gained wider acceptance, systems have a clear mandate to maximize its value for those high-risk patients who respond insufficiently to clinic care. The present study provides evidence supporting comprehensive telehealth for PPDM within the VHA, but also presents a template for how other systems might use existing resources to improve the management of PPDM and other hard-to-treat conditions.

While our focus on examining practical, comprehensive telehealth specifically for PPDM is novel, the findings also add to the broader telehealth literature in T2D. The between-arm HbA_{1c} effect we observed (−0.61%) is notable given our active-comparator design and the relatively modest effects reported in recent systematic reviews of telehealth interventions (mean HbA_{1c} benefit vs usual care, −0.4%).^{51,52} In particular, prior RCTs

examining comprehensive interventions for T2D have not lowered HbA_{1c} level²⁰⁻²⁵; these include studies that specifically sought to examine multicomponent interventions vs usual care in pragmatic settings (non-VHA), with neutral results.²⁰⁻²²

Limitations

Despite efforts to oversample women, the population demographics may limit generalizability. However, the cohort's high proportion of Black participants (72.0%) is a strength and may suggest that the pandemic-induced shift to telehealth need not exacerbate health care inequities.^{53,54} The studied interventions were designed for practical delivery within the VHA, which may limit generalizability to systems lacking capacity for nurse-delivered telehealth, integrated mental health, and dietitian services; nevertheless, the idea of designing telehealth interventions to leverage available resources is broadly applicable. The VHA costs may not fully generalize, but the between-arm cost difference may be more translatable.

While clinical intervention delivery continued unimpeded during the pandemic, the missing data frequency was higher than expected at 12 months; however, the sensitivity analyses with multiple imputation and inclusion of clinical HbA_{1c} data support the validity of the findings. Of note, participants could not be blinded to randomization status, which leaves potential for bias, especially pertaining to subjective survey measures.

This study was not designed to evaluate the effectiveness of each individual component of the comprehensive intervention. Future mediator analyses will examine how each component contributes to the overall intervention effect. Finally, the comprehensive telehealth intervention does not account for all contributors to PPDM, including social determinants of health.

Conclusions

Findings from this randomized clinical trial showed that compared with a simpler telehealth approach, a comprehensive telehealth intervention improved HbA_{1c} level and other outcomes in patients with PPDM. Because this comprehensive telehealth intervention was delivered by clinical staff using existing resources, it may warrant clinical implementation in systems with appropriate infrastructure. More broadly, this study provides valuable comparative evidence that may help systems maximize the value of telehealth during the COVID-19 pandemic and beyond.

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