TeleHealth Improves Diabetes Self-Management in an Underserved Community

Diabetes TeleCare

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OBJECTIVE — To conduct a 1-year randomized clinical trial to evaluate a remote comprehensive diabetes self-management education (DSME) intervention, Diabetes TeleCare, administered by a dietitian and nurse/certified diabetes educator (CDE) in the setting of a federally qualified health center (FQHC) in rural South Carolina.

RESEARCH DESIGN AND METHODS — Participants were recruited from three member health centers of an FQHC and were randomized to either Diabetes TeleCare, a 12-month, 13-session curriculum delivered using telehealth strategies, or usual care.

RESULTS — Mixed linear regression model results for repeated measures showed a significant reduction in glycated hemoglobin (GHb) in the Diabetes TeleCare group from baseline to 6 and 12 months (9.4 ± 0.3, 8.3 ± 0.3, and 8.2 ± 0.4, respectively) compared with usual care (8.8 ± 0.3, 8.6 ± 0.3, and 8.6 ± 0.3, respectively). LDL cholesterol was reduced at 12 months in the Diabetes TeleCare group compared with usual care. Although not part of the original study design, GHb was reduced from baseline to 12 and 24 months in the Diabetes TeleCare group (9.2 ± 0.4, 7.4 ± 0.5, and 7.6 ± 0.5, respectively) compared with usual care (8.7 ± 0.4, 8.1 ± 0.4, and 8.1 ± 0.5, respectively) in a post hoc analysis of a subset of the randomized sample who completed a 24-month follow-up visit.

CONCLUSIONS — Telehealth effectively created access to successfully conduct a 1-year remote DSME by a nurse CDE and dietitian that improved metabolic control and reduced cardiovascular risk in an ethnically diverse and rural population.

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The translation of efficacy trials (1,2) that improve metabolic control for adults with type 2 diabetes to communities is of major interest, given the variable adherence to established diabetes clinical practice guidelines (3,4). This is particularly important for African American adults with diabetes living in rural communities with poor access to specialized care, where the prevalence of diabetes and their complications is almost 50% higher than that of non-Hispanic whites (5). The role of technology to facilitate the delivery of diabetes self-management education (DSME) is gaining attention. However, a relatively small number of studies have been published, including Internet-based interventions, telephonic support, home-based interventions, and telemedicine sessions in a clinic setting (6–9).

We conducted a 1-year randomized clinical trial to evaluate a remote comprehensive DSME intervention administered by a dietitian (A.D.H.) and nurse diabetes educator (certified diabetes educator [CDE]) designed to improve adherence to American Diabetes Association (ADA) guidelines, which included the availability of a remote retinal assessment. Telehealth strategies, including interactive videoconferencing, telephone (both cellular and land lines), fax line, and a telehealth-enabled retinal camera, were used in the setting of a community health center as a means to bridge barriers of access and transportation for ethnically diverse adults with diabetes who reside in rural South Carolina. The primary goal of this clinical trial was to improve glycemic control and cardiovascular risk through improved diabetes self-management.

RESEARCH DESIGN AND METHODS

— Patients were recruited from three community health centers in northeast South Carolina. The health centers were members of CareSouth Carolina, a federally qualified health center (FQHC) headquartered in Hartsville, South Carolina. The sites were >100 miles from the University of South Carolina and were identified with assistance from the South Carolina Primary Health Care Association, a consortium of FQHCs across the state. FQHCs must serve an underserved area or population, offer a sliding fee scale, provide comprehensive services, have an ongoing quality-assurance program, and have a governing board of directors (10). A second FQHC was initially included but withdrew early in the recruitment process due to unspecified administrative issues. This resulted in a revised final sample size (see the "Sample size and statistical analysis" section below).

Inclusion criteria were GHb >7%, age ≥35 years, having been seen within

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the last year at the community health center, having a clinical diagnosis of diabetes, and being able and willing to participate in a 1-year clinical trial. Exclusion criteria were BMI <25 kg/m^2 (based on self-reported height and weight), pregnancy, and acute or chronic illness that prevented safe participation in the study. Recruitment results, published elsewhere (11), describe the process that occurred in three consecutive waves during April 2005 to October 2006. A billing data extraction yielded 1,984 patients with diabetes, and 43.8% were eligible at medical record review. Telephone contact was attempted, and, of those eligible and interested, 165 completed two in-person screening visits and were randomized. The appropriate institutional review board approved the protocol, and all participants provided written informed consent.

Table 1—*The Diabetes TeleCare intervention curriculum*

Intervention session	Session type	Delivery method
Welcome & Health Eating	Group	In person
Goal Setting	Individual	Telemedicine
Start Stepping	Group	Telemedicine
Be a Food Detective	Group	Telemedicine
Know Your Medicines	Group	Telemedicine
Shop Smart	Group	In-person at local grocery store
Stick With It: Positive Thinking	Group	Telemedicine
Foot Care Basics & Know Your Numbers	Individual	Telemedicine
Healthy Eating Out	Group	Telemedicine
Stress Management	Group	Telemedicine
Keeping Well & Healthy	Individual	Telemedicine
Community Resources, Social Support	Group	Telemedicine
Put It All Together	Group	In person

Intervention

Diabetes TeleCare was a 12-month DSME intervention with 13 sessions, 3 individual and 10 group. Two sessions (one individual and one group) were held in the first month for an intervention "jump start." Three group sessions were conducted in-person; all others were conducted by interactive videoconferencing by the self-management education team (a nurse/CDE and a dietitian) who were at the academic health center while the participants were at the primary-care clinic. Make-up sessions were conducted on the telephone. Given the remote location of the clinic sites, a licensed practical nurse (LPN) was hired to coordinate in-person administrative functions at the clinic sites, to serve as a "hands-on" assistant for the self-management team during intervention sessions, and to perform standardized data collection.

Two theoretical models provided the basis of the intervention delivery: the Health Belief Model (12) and the Transtheoretical Model (13), with group and individualized goal setting utilized at each session. Participants completed logs recording the results of self-monitored blood glucose, diet, and physical activity (with use of pedometer to track steps). Initially, self-monitoring was done daily, followed by decreased frequency based on progress toward intervention goals. The intervention content was created using three existing, evidence-based sources: *1*) the Pounds Off With Empowerment materials (14) (a modified version of the Diabetes Prevention Program Lifestyle Change materials) (15), *2*) the ADA clinical practice guidelines (16), and *3*) The Michigan Diabetes Research and Training Center's Life with Diabetes Curriculum (17). Modifications included considerations for a low-literacy, rural South Carolina population. An outline of the intervention curriculum is provided in Table 1.

Additionally, intervention participants were offered retinal imaging in the primary-care setting when they were due for their annual eye exam. This was optional, as some participants preferred to seek an eye exam by their eye care provider. A retinal camera (Digiscope-EyeTel Imaging, Columbia, MD) was placed in one of three participating primary-care practices. The LPN was trained to pharmacologically dilate the pupil of each eye (1% tropicamide, one drop) and conduct the exam. Electronically stored retinal images were sent after hours via fax line to a remote reading center, and images were interpreted by an ophthalmologist (I.Z.G.). Reading services were contracted, which included a quality-control process for standardization over time. Referrals for any retinal abnormality or ungradeable images were scheduled with the nearest ophthalmologist (~50 miles away), and transportation was provided at no charge.

Usual care consisted of one 20-min diabetes education session, using ADA materials, conducted individually at the time of randomization by the LPN. No other education/support for diabetes was given. However, access to existing services at the community health centers continued, including a diabetes collaborative (sponsored by the Bureau of Primary Health Care/Health Resources and Services Administration), care managers available for education/goal setting, and a nurse practitioner to help patients with the highest GHb levels.

Outcomes

Analysis of the primary outcome (GHb) as well as secondary outcomes (LDL cholesterol and the albumin-to-creatinine ratio) was performed on an Olympus AU400 via immunoassay/absorption spectroscopy. Additional secondary outcomes included blood pressure, measured using the Omron HEM-907 IntelliSense blood pressure monitor.

Blood pressure was measured three times, and the average of the second and third readings was used. Weight was measured to the nearest 0.5 lb using a Detecto balance-beam scale. BMI was calculated from weight and the square of height measured with a Detecto stadiometer measured to the nearest 0.1 cm. Natural waist circumference measurements were made using the Rosscraft nontension flexible steel tape measure and recorded to the nearest 0.1 cm. Circumference was measured twice; if the measurements differed by >1 cm, a third measurement was made. Additionally, data were collected on demographics; medical history; medications; knowledge, beliefs, and behaviors related to diabetes; usual diet; physical activity (10-day pedometer log); visual function and self-report of eye exam in the last year; health utilities; and cost.

Outcomes were collected on all randomized participants at baseline and 6 and 12 months. Participants were given a gift card for each completed visit. The

LPN was trained on standardized data collection before the start of recruitment. Retraining took place prior to each subsequent data collection period, and direct observation of the LPN occurred during all active data collection periods. Not part of the original study design, we conducted a brief 24-month measurement visit on approximately two-thirds of the randomized sample. We had to exclude the first 58 randomized patients as their 24-month window had expired by the time the measurement visits commenced.

Sample size and statistical analysis

The original intended sample size was 200, based on a power of 0.8, an α of 0.05, and an effect size of 0.5% change in GHb as the primary outcomes, with detectable clinically relevant changes in secondary outcomes and allowing conservatively for 30% loss to follow-up. However, due to withdrawal of one FQHC early in the participant recruitment process, we re-evaluated our recruitment requirements allowing for only 19% loss to follow-up. This was a practical decision, based on actual experience of our group of 81% retention in a similar study (18).

Analyses were conducted with SAS version 9.1 (SAS Institute, Cary, NC). Linear mixed models (PROC MIXED) for repeated measures tested for differences for each outcome. These models used group (intervention/usual care) as the predictor of interest, controlling for potential confounders. Planned contrasts of group differences were used to identify significant changes between groups from baseline to 6 months and baseline to 12 months. Post hoc analyses, with recognized power limitations, were conducted separately on a subsample with data from the 24-month visit. Consistent with the original design criteria, *P* values <0.05 were regarded as significant.

Table 2—*Baseline characteristics of a randomized sample* (n = *165*)

	Intervention	Usual care	*P* value
n	85	80	
Race (%)			0.72
African American/other	75.3	72.5	
Non-Hispanic white	24.7	27.5	
Female (%)	72.9	76.3	0.72
Age (years)	59.9 ± 9.4	59.2 ± 9.3	0.65
Diabetes medication use (%)			0.13
No diabetes medication	0	5.1	
Oral medication only	51.3	43.0	
Insulin only	16.3	22.8	
Oral medication and insulin	32.5	29.1	
Duration of diabetes (years)	8.5 ± 6.6	10.3 ± 8.1	0.13
Education (%)			0.17
Less than high school	37.0	46.2	
High school graduate/GED	37.0	41.0	
Some college or more	17.3	10.3	
Other	8.6	2.6	
Income (%)			0.42
<$5,000	12.7	16.0	
$5,000–$14,999	51.9	53.3	
$15,000–$29,000	16.5	21.3	
$30,000–$59,000	10.1	6.7	
≥$60,000	8.9	2.7	
Insurance (%)			0.19
Medicare and private	8.6	7.6	
Medicare/Medicaid	43.2	39.2	
No health insurance	19.8	34.2	
Private health insurance/HMO	28.4	19.0	
GHb (mg/dl)	9.3 ± 1.9	8.9 ± 1.8	0.19
LDL cholesterol (mg/dl)	108.6 ± 36.2	107.1 ± 33.2	0.78
Albumin-to-creatinine ratio (mg/g)	91.1 ± 210.2	96.9 ± 236.0	0.87
Systolic blood pressure (mmHg)	135.3 ± 21.2	138.5 ± 19.9	0.33
Diastolic blood pressure (mmHg)	76.2 ± 12.0	74.8 ± 10.4	0.42
Waist circumference (cm)	115.1 ± 15.7	112.5 ± 18.4	0.35
Weight (kg)	101.3 ± 21.7	96.6 ± 22.3	0.17
BMI (kg/m^2)	37.1 ± 8.1	35.9 ± 7.6	0.33
BMI category (%)			0.53
Normal (18.5–24.9)	3.6	1.3	
Overweight (25.0–29.9)	16.7	23.7	
Class I obesity (30–34.9)	23.8	29.0	
Class II obesity (35.0–39.9)	17.9	17.1	
Class III obesity (≥40)	38.1	29.0	
Used study provided transportation (%)	38.8	36.7	0.87
Self-reported GHb having been checked in last 6 months (%)	82.5	81.0	0.96
Self-reported checking of blood glucose more than once a week (%)	80.8	79.2	0.84
Self-reported having received eye exam in the last year (baseline) (%)	51.2	46.3	0.29

RESULTS — Table 2 demonstrates baseline characteristics of the randomized sample. This sample was comprised of overweight and obese adults, primarily African American and female with long-standing diabetes controlled primarily with either oral medications only or a combination of oral medications and insulin. Educational attainment and self-reported income were low, with two-fifths of the sample having Medicare/Medicaid. Baseline metabolic indicators were all above recommendations as set forth by the ADA Standards of Medical Care in Diabetes (19). More than one-third of the sample required transportation to participate. The majority of the sample reported having their GHb checked by a health professional in the last 6 months and checking their blood glucose at home one time per week or

Table 3—*Least square means for primary and secondary outcomes at baseline and 6 and 12 months by randomization status (estimate ± SE) and* P *values from the corresponding mixed model* (n = *165*)

	Intervention	Usual care	*P* value*
n	85	80	
GHb (%)			
Baseline	9.4 ± 0.3	8.8 ± 0.3	
6 month	8.3 ± 0.3	8.6 ± 0.3	0.003
12 month	8.2 ± 0.4	8.6 ± 0.3	0.004
LDL cholesterol (mg/dl)			
Baseline	103.0 ± 6.5	102.5 ± 6.2	
6 month	96.7 ± 6.5	100.3 ± 6.5	0.50
12 month	89.7 ± 6.9	103.1 ± 6.8	0.02
Systolic blood pressure (mmHg)			
Baseline	130.8 ± 3.6	134.6 ± 3.4	
6 month	133.0 ± 3.6	137.8 ± 3.6	0.89
12 month	127.6 ± 4.0	130.9 ± 3.8	0.76
Diastolic blood pressure (mmHg)			
Baseline	72.7 ± 2.1	73.0 ± 2.0	
6 month	72.3 ± 2.1	75.4 ± 2.0	0.12
12 month	70.2 ± 2.2	71.4 ± 2.2	0.64
BMI (kg/m^2)			
Baseline	36.0 ± 1.4	34.5 ± 1.4	
6 month	35.7 ± 1.4	34.7 ± 1.4	0.07
12 month	35.8 ± 1.4	34.3 ± 1.4	0.73
Waist circumference (cm)			
Baseline	115.9 ± 3.0	113.8 ± 2.9	
6 month	114.9 ± 2.9	111.4 ± 2.8	0.17
12 month	115.2 ± 3.0	110.8 ± 2.9	0.33
Albumin-to-creatinine ratio (log transformed)			
Baseline	2.9 ± 0.3	2.8 ± 0.3	
6 month	2.9 ± 0.3	3.0 ± 0.3	0.12
12 month	3.0 ± 0.3	2.7 ± 0.3	0.80

*P value from mixed model adjusted for all outcomes in the table included randomization, visit type, randomization × visit type, wave, clinic, insurance, age, race, sex, BMI (not included in model with BMI as outcome), diabetes duration, self-report taking diabetes medication, self-report taking prescribed cholesterol medication, self-report taking prescribed blood pressure medication, and self-report of any eye exam in the last year.

more, while roughly half reported receiving an eye exam in the last year.

Table 3 provides least square means by intervention status over time from the linear mixed models for the primary and secondary outcomes and corresponding *P* values. The improvement in glycated hemoglobin was significantly greater in the intervention group compared with usual care from baseline to 6 and 12 months (Fig. 1). Improvement in LDL cholesterol was significantly greater in the intervention group compared with usual care from baseline to 12 months only. There was no difference in improvement in systolic blood pressure, diastolic blood pressure, BMI, waist circumference, or albumin-to-creatinine ratio. At the 12-month measurement visit, a significantly greater proportion of participants in the intervention group reported receiving an eye exam during the 1-year study (81.2%), as compared with usual care (38.8%) ($P < 0.0001$). However, having an eye exam during the study period compared with not having an eye exam was not associated with glycated hemoglobin in univariate analysis ($P = 0.84$) or in the final mixed model ($P = 0.88$).

There were no significant differences in baseline characteristics between those included and not included in the 24-month post hoc analysis. Mixed-model results showed a significantly greater improvement in GHb in the intervention group (baseline 9.2 ± 0.4, 6 months 8.3 ± 0.5, 12 months 7.4 ± 0.5, and 24 months 7.6 ± 0.5) compared with usual care (baseline 8.7 ± 0.4, 6 months 8.6 ± 0.4, 12 months 8.1 ± 0.4, and 24 months 8.1 ± 0.5) from baseline to 6 months ($P = 0.05$), 12 months ($P = 0.004$), and 24 months ($P = 0.04$) (data not shown in table form).

CONCLUSIONS — This randomized clinical trial evaluated Diabetes TeleCare, a 1-year, remote, evidence-based DSME intervention conducted primarily with interactive video conferencing to link diabetes interventionists with adults with type 2 diabetes in rural and underserved areas where such services were unavailable. Other telehealth strategies were utilized to facilitate communication in providing DSME according to clinical care guidelines such as telephones and cell phones for make-up educational sessions and fax lines to send retinal images acquired in the primary-care setting for interpretation.

The withdrawal of a FQHC early in the recruitment process prevented the collection of demographic data, which resulted in the inability to compare patients from the nonparticipating site to those that participated. However, all clinics were members of the same umbrella or-

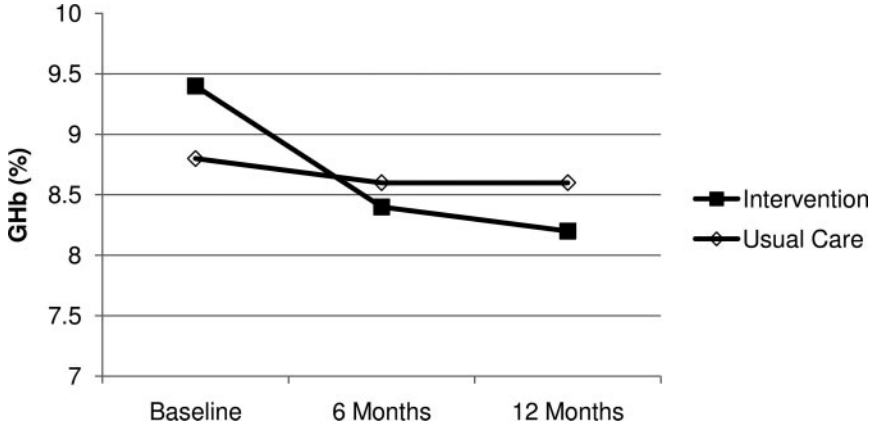

Figure 1—*Comparison of GHb in intervention and control groups.*

ganization for FQHCs in the state, and a comparison of county-level demographic information for the participating and nonparticipating sites was similar. A significant improvement of GHb at 6 and 12 months and LDL cholesterol at 12 months is proof of concept that Diabetes TeleCare is effective in an underserved and rural setting.

In the post hoc analysis, even with the modest sample size, the effect of the intervention appeared to continue with an improved GHb in the intervention group compared with the control group. Since the control arm (usual care) was represented by an ongoing educational program administered by a certified health educator, the improvement in metabolic control of participants randomized to the Diabetes TeleCare intervention was a value-added approach compared with standard DSME. A weakness of the intervention is that BMI, weight, and waist circumference did not improve, suggesting that improved medication adherence was important. Subsequent interventions will include motivational interviewing that may result in improved behavioral outcomes. Another weakness of the study was the paucity of male participants. However, this sex difference was not unique to this study but reflected the underlying demographics of the primary-care practices.

Four important factors may be related to the success of the Diabetes TeleCare intervention: high participant retention, modification of materials for cultural competency, coordinating administrative functions with the primary-care centers, and the successful personalized interactions during group education sessions enabled by video conferencing. Retention rates at 6 and 12 months were 90.9 and 82.4%, respectively, and were attributed to factors such as reminder telephone calls and mailings and is described fully elsewhere (18). Coordination of key functions at the primary-care practice relating to the Diabetes TeleCare intervention, research data management, clinic systems of care, and use of telehealth equipment was managed by the LPN who worked at the primary-care sites. The LPN was critical to effective study operations and was paramount to the relationship between the academic center and the community health organization.

Improvements in metabolic control were facilitated by telehealth and, specifically, interactive video conferencing to create access to a dietitian and the CDE. Diabetes TeleCare, utilizing single and group sessions, resulted in improvements in GHb that were greater in magnitude compared with a relatively more expensive individual telehealth home-based intervention (9,20), as well as other telehealth interventions (6–8).

In summary, multicomponent telehealth strategies were effectively utilized to successfully conduct a comprehensive remote DSME by physician extenders (CDE and dietitian) in a rural, underserved, and ethnically diverse primary-care setting, which improved metabolic control of adults with type 2 diabetes. In addition, this novel approach may be an effective and efficient means to extend the reach of a CDE or dietitian to areas and populations that would greatly benefit by improved metabolic control.

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R.M.D. provided oversight to the research and prepared the manuscript, A.D.H. conducted research and analyses and assisted in the preparation of the manuscript, M.M.S. participated in the research and conducted a literature review for the manuscript, W.H.H. conducted the cost analysis and assisted in the preparation of the manuscript, I.E.Z.-G. interpreted remote retinal images and reviewed the manuscript, and E.J.M.-D. reviewed and edited the manuscript.

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