ORIGINAL RESEARCH

A Cluster Randomized Trial Comparing Strategies for Translating Self-Management Support into Primary Care Practices

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Introduction: **Self-management support (SMS) is a key factor in diabetes care, but true SMS has not been widely adopted by primary care practices. Interactive behavior-change technology (IBCT) can provide efficient methods for adoption of SMS in primary care. Practice facilitation has been effective in assisting practices in implementing complex evidence-based interventions, such as SMS. This study was designed to study the incremental impact of practice education, the Connection to Health (CTH) IBCT tool, and practice facilitation as approaches to enhance the translation of SMS for patients with diabetes in primary care practices.**

Methods: **A cluster-randomized trial compared the effectiveness of 3 implementation strategies for enhancing SMS for patients with diabetes in 36 primary care practices: 1) SMS education (SMS-ED); 2) SMS-ED plus CTH availability (CTH); and 3) SMS-ED, CTH availability, plus brief practice facilitation (CTH + PF). Outcomes including hemoglobin A1c (HbA1c) levels and SMS activities were assessed at 18 months post study initiation in a random sample of patients through medical record reviews.**

Results: **A total of 488 patients enrolled in the CTH system (141 CTH, 347 CTH + PF). In the intent-to-treat analysis of patients with medical record reviews, HbA1c slopes did not differ between study arms (CTH vs SMS-ED: *P* = .2243, CTH + PF vs SMS-ED: *P* = .8601). However, patients from practices in the CTH + PF arm who used CTH showed significantly improved HbA1c trajectories over time compared with patients from SMS-ED practices (*P* = .0422). SMS activities were significantly increased in CTH and CTH + PF study arms compared with SMS-ED (CTH vs SMS-ED: *P* = .0223, CTH + PF vs SMS-ED: *P* = .0013). The impact of CTH on SMS activities was a significant mediator of the impact of the CTH and CTH + PF interventions on HbA1c.**

Conclusion: **An interactive behavior change technology tool such as CTH can increase primary care practice SMS activities and improve patient HbA1c levels. Even brief practice facilitation assists practices in implementing SMS. (J Am Board Fam Med 2019;32:341–352.)**

Keywords: **Behavioral Medicine, Behavior Therapy, Chronic Disease, Counseling, Disease Management, Glycated Hemoglobin A, Health Promotion, Life Style, Obesity, Patient-Centered Care, Primary Health Care, Self Care, Self-Management, Type 2 Diabetes Mellitus**

Most patients with type 2 diabetes mellitus (T2DM) in the United States receive diabetes care in primary care settings. Self-management support (SMS) is a key factor in diabetes care, focusing on the central

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role of patients in managing their illness.[1–4] SMS provides tools and skills for patients to manage their care, typically with a focus on medication adherence, diet, exercise, chronic disease management, and other risk-related behaviors. This includes shared decision making, goal setting, and action planning around key health issues. However, while some forms of patient education are made available, true SMS has not been widely or effectively adopted by primary care practices,[5,6] and SMS activities vary according to certain practice demographics and other characteristics.[7] Lack of SMS support for patients with diabetes or other chronic illnesses has been attributed to a range of system-level barriers, including a lack of training in the appropriate skills, poor reimbursement for SMS activities, and the chaos and competing demands of primary care.[8–10] In addition, few tools are available to assist practices with SMS.

Interactive behavior-change technology (IBCT) can provide efficient methods for the adoption of SMS interventions in primary care for patients with diabetes and related health risk behaviors,[11,12] as they can provide a convenient, time-efficient way to provide tailored, individualized support and resources for patients.[11,13,14] The major goals of IBCT are to: 1) detect and then monitor patient needs for SMS over time, 2) prompt clinician/patient discussions to engage patients in behavior change, 3) establish individualized priorities for identified problems, 4) provide options for intervention at the point of care, and 5) monitor success over time and prompt followups.[11,13] There is strong evidence that automated and Web-based programs can effectively support diabetes self management,[15] including healthful eating/weight management,[16–19] increasing physical activity,[20–22] reducing depression symptoms, and smoking cessation.[23,24] Randomized trials have been conducted using IBCT programs for diabetes self-management with positive results.[25,26] However, to our knowledge no comprehensive system exists that includes prevention and multiple chronic disease monitoring and intervention that is based on practical, well-documented measures and directly tied to actionable resources and recommendations for clinicians and patients.[6,27–33] Most current IBCT SMS programs are largely informational, require high literacy, are limited to health-risk assessment without goal setting, action planning, or follow-up, and do not emphasize patient-physician collaboration.[34,35]

Connection to Health (CTH) is a comprehensive, evidence-based SMS program that assists practices with the implementation of SMS for diabetes and other chronic illnesses through IBCT. CTH has the potential of providing practices with a systematized, structured, and streamlined SMS program for practice teams and patients to use across multiple chronic illnesses and health behaviors. Patients complete an initial automated online assessment covering multiple issues related to diabetes and comorbid conditions using abbreviated versions of state-of-the-art measures, each with cut-points defining a flagged area for concern. Patients automatically receive a scored summary report, which they are asked to review and identify potential priority areas. A separate clinician report includes decision support tools and intervention options for the clinician for each flagged area on the profile. These reports lead to a clinical discussion, with action planning, goal setting, and problem solving[36] structured through the same CTH program. CTH also includes online patient resources and tips to improve diabetes management.

Implementation of SMS, especially in a real-world practice setting, involves relatively complex changes in workflow and process and can be difficult for practices without support. Practice facilitation has been effective in assisting practices in implementing organizational changes and evidence-based interventions.[37–42] A facilitator uses sound quality improvement processes and tools to assist a practice in tailoring a program to fit their unique practice situation, resources, and culture, improving its implementation and its sustainability over time.

This study was designed to study the incremental impact of practice education, the CTH SMS tool, and practice facilitation as approaches to enhance the translation of SMS for patients with T2DM in diverse primary care practices. We used the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework to guide our evaluation. RE-AIM is designed to enhance the quality, speed, and public health impact of efforts to translate research into practice.[43–48] In this study we place particular emphasis on the Reach, Effectiveness, and Implementation domains of RE-AIM. The hypotheses were that 1) practices with only a practice SMS educational intervention would po-

Table 1. Approaches to Implementing Self-Management Support for Type 2 Diabetes—Program Elements across Project Arms (2012–2018)

Program Element	SMS-ED	CTH	CTH + F
CTH computerized intervention program	No	Yes	Yes
Technical assistance with CTH implementation	No	Yes	Yes
Basic instructions on use of CTH	No	Yes	Yes
Assessment of baseline SMS and diabetes care activities	Yes	Yes	Yes
Feedback of assessment and recommendations for practice	No	No	Yes
SMS education sessions with practice	Yes	Yes	Yes
Website with SMS resources	Yes	Yes	Yes
Practice facilitation:	No	No	Yes
Improvement team meetings: 4 over approximately 3 months.			
Workflow revision to implement CTH			
Email contacts, other assistance between improvement team meetings and after 3 months as needed			
Ongoing feedback of data regarding CTH usage			

CTH, Connection to Health; CTH + PF, Connection to Health with Practice Facilitation; SMS, self-management support; SMS-ED, self-management support education.

tentially improve SMS activities, but not substantially, 2) CTH would be an effective tool for improving SMS activities and potentially patient outcomes, and 3) practice facilitation would increase the *uptake* and *effectiveness* of both SMS and CTH.

Methods

Design

We designed a 3-arm, cluster-randomized trial to compare the effectiveness of 3 implementation strategies for enhancing SMS for patients with T2DM in primary care practices using CTH. Outcomes were assessed at 18 months post study initiation. The details of the study protocol have been described elsewhere[49] and are summarized in Table 1.

Sample

We recruited 36 primary care practices, 18 each in Colorado and California to assure a wide diversity of practices. Inclusion criteria were family medicine or general internal medicine practices with a minimum of 80 patients with T2DM, with all clinicians agreeing to participate. Covariate constrained randomization procedures were used[50,51] to ensure acceptable study arm balance on key practice characteristics (number of providers, % Medicaid, % uninsured, number of diabetic patients, % of diabetic patients with hemoglobin A1c [HbA1c] >9) that might impact the outcomes.

Interventions

SMS Education Arm

The SMS-ED arm served as an attention control (see Table 1). Project staff met onsite with practice clinicians and staff members for 2 1-hour sessions to discuss key aspects of SMS. These SMS sessions were standardized across all study arms and topics included describing the differences between SMS and patient education, the evidence for providing SMS in primary care, and patient-centered counseling techniques. Practices also had access to a Web site with SMS resources for both patients and the practice, but they did not have access to the CTH program nor to any further SMS implementation support.

CTH Arm

In addition to educational sessions on SMS and the web-based resources, practices in this arm received the full use of the CTH program, with basic technical assistance on program operation. The technical assistance covered instruction on CTH, assistance for any technical problems in incorporating the CTH platform into the practice's computer systems, and answering any questions regarding the use of CTH. Practices did not, however, receive any practice facilitation to assist with CTH adoption and implementation.

CTH plus Facilitation (CTH + PF) Arm

This arm included the same intervention components as CTH, but added short-term practice facilitation by a trained practice facilitator that focused on CTH adoption and implementation. The active practice facilitation phase included 4 practice facilitation meetings, to assist in developing a CTH adoption plan. Active facilitation was followed by monthly calls by the facilitator to review data regarding the practice's use of CTH. A brief "booster" facilitation session could also be scheduled to address subsequent problems.

Patient Samples

Medical record reviews were conducted by research staff separate from the intervention team on a random sample of patients with T2DM who had received care in each practice for at least 1 year at baseline. Since allocation of patients occurred at the level of the practice, all patients within a practice were assigned to the same treatment condition, regardless of the extent to which the individual patient used the tools provided. Although the intervention could potentially impact the entire population of patients with T2DM, each practice in the CTH and CTH + PF arms selectively utilized CTH with patients. Therefore, practices in each of the 2 arms with CTH had patients who were and were not exposed to CTH. To preserve ITT approaches, evaluate the reach of CTH (CTH and CTH + PF arms only), and alleviate potential selection bias at the level of individual patient recruitment[52–55] (ie, providers may selectively recommend CTH to some patients and not others, based on patient characteristics such as blood glucose control, perceived patient motivation, etc.), we evaluated 2 overlapping patient samples in each practice. The first was a random sample from the population of all patients with T2DM who had a HbA1c done during the 18 months before the practice baseline date and at least 1 visit to the practice from baseline to 12 months after baseline, whether or not they participated in "CTH Intent to Treat" Sample. This sample enabled us to examine the reach of CTH as well as the effectiveness of each practice-based intervention on the primary outcome variables in the population of patients with T2DM. A second sample in each practice was comprised of only those patients with diabetes who completed the CTH assessment—the "CTH Per Protocol Sample." It should be noted that these 2 samples were not independent of each other; for example, many in the CTH Per Protocol sample were included randomly in the intent to treat sample.

Measures

Primary Outcomes

Primary Outcomes, including HbA1c, systolic and diastolic blood pressure, and body mass index (BMI), were abstracted via medical record reviews covering 18 months before baseline through 18 months post baseline. For each, the last measure before baseline was used as the baseline measure.

SMS Activities: Process of Care

SMS activities: process of care elements were also assessed in medical record review, including evidence of SMS-related discussions, collaborative goal setting, action planning around patient goals, collaborative problem solving regarding the action planning process, use of community resources to assist in goal attainment, and ongoing monitoring of progress on identified goals. SMS-related discussions were grouped into diabetes-related (medication management, nutrition, exercise, and diabetes management) and other behavioral health discussions (mental health, social problems, alcohol or substance abuse). The total number of SMS activities noted in the chart were summed for the 18-month periods before and following baseline. This does not include SMS activities that occurred out of the medical practice and were not noted in the chart.

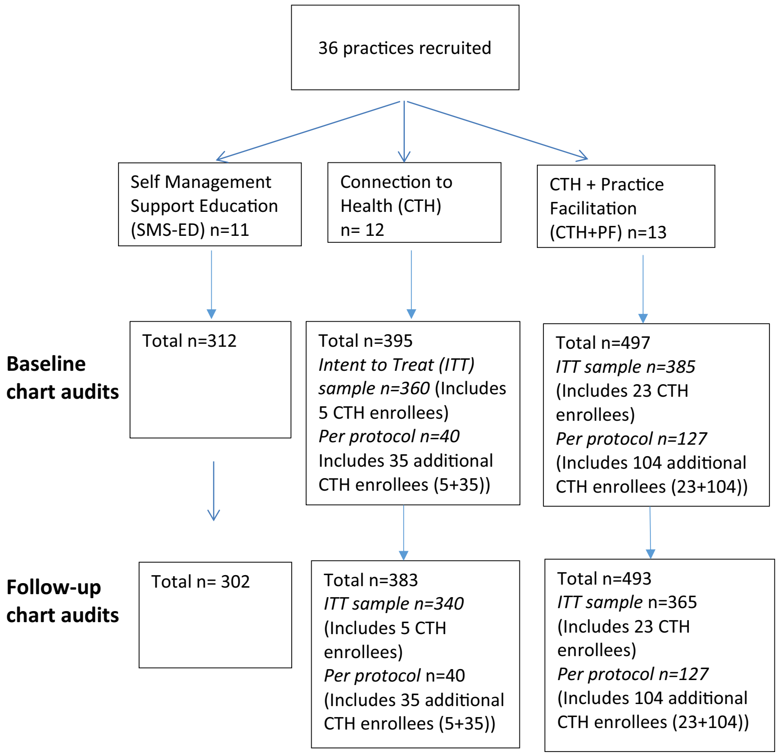
Practice Characteristics

Practice characteristics were described and examined as potential confounders and moderators in analyses, including level of quality improvement experience, level of patient-centered medical home (PCMH) implementation, practice size, setting (rural/urban), type of practice organization, baseline performance characteristics related to diabetes, percentage of minority patients in the practice, and percentage of Medicaid or uninsured patients.

Data Analysis

For this cluster randomized trial, descriptive statistics, χ^2 tests, and one-way ANOVAs were computed for baseline patient and practice characteristics, initially testing for differences between 1)

Figure 1. Connection to health project CONSORT diagram. CTH, Connection to Health; CTH+PF; Connection to Health with practice facilitation; SMS, self-management support; SMS-ED, self-management support education.



intervention arms, and 2) CTH participants versus nonparticipants. The reach (from RE-AIM) of CTH was assessed in the CTH and CTH + PF arms as the proportion of patients in the ITT sample who were enrolled in CTH. A continuity-corrected χ^2 test was used to assess differences in reach between the CTH and CTH + PF arms. Patient-level covariates were screened in bivariate analyses and included in multivariate analysis if they were sociodemographic variables (age, gender), related to the outcome at $P < .2$, or differed between treatment arms. Patient-level covariates screened in all analyses included age, gender, BMI, systolic and diastolic blood pressure, comorbid diagnoses (hypertension, hyperlipidemia, pulmonary, cardiovascular disease, depression, medications [hypertension, lipids, oral diabetic, insulin]). We employed methods that utilized all available data, assuming ignorable missingness.[56–59] We used general (or generalized, ie, Poisson) linear mixed models with random effects for patient and practice to incorporate both hierarchical (patients within practices) and longitudinal (repeated measures on patients over time) data structures.[52–55,60–62] For longitudinal analysis of patient-level outcomes, baseline is defined as the day of the first training meeting the practice had with the study team and is the same for all patients in that practice. For clinical measures, time is coded as days since baseline, converted to year for interpretability. For SMS activities, time is coded as pre (time = 0) or post-baseline (time = 1). Hypothesis tests were 2-sided with α = 0.05 or P values reported. All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC).

Results

The CONSORT diagram of practice and patient flow in the study is shown in Figure 1. All 36 practices completed the study.

ITT and Reach

From practice-generated lists of patients with diabetes, a random sample of 1057 charts were audited for diabetes processes of care and outcomes as part of the ITT sample. Of the total patients in the ITT sample, 5 of 360 (1.4%) patients from the CTH arm were enrolled in the CTH system, and 23 of

Table 2. Baseline Practice and Patient Characteristics

Practice Characteristics	SMS-ED	CTH	CTH + PF
N	11	12	13
Practice Type Federally Qualified Health Center, n (%)	9 (81.8%)	9 (75%)	9 (69.2%)
Number of clinicians, mean (SD)	7.4 (3.4)	7.3 (4.1)	6.1 (4.3)
% Medicaid, mean (SD)	41.5 (21.5)	35.1 (22.0)	38.7 (18.4)
% Uninsured, mean (SD)	27.3 (17.9	28.2 (19.1)	25.6 (21.2)
% HbA1c > 9, mean (SD)	28.4 (11.1)	22.9 (9.1)	28.5 (5.6)
Number of diabetic patients, mean (SD)	589.8 (392.4	541.3 (385.2)	408.9 (309.0)
PCMH Status:			
Some implementation, but not recognition, n (%)	1 (9.1%)	3 (25.0%)	4 (30.8%)
PCMH recognition, n (%)	8 (72.7%)	8 (66.7%)	8 (61.5%)

CTH, Connection to Health; CTH + PF, Connection to Health with Practice Facilitation; HbA1c, Hemoglobin A1c; PCMH, patient centered medical home; SMS, self-management support; SMS-ED, self-management support education; SD, standard deviation.

385 (6.0%) patients from the CTH + PF arm were enrolled in the CTH system (P = .002).

Per Protocol

All patients enrolled in the CTH system were identified by medical record number in each practice. An additional random sample of these patients (up to 30 per practice, if available) was drawn to examine the effectiveness of CTH among enrolled patients (per protocol). Thus, charts from an additional 139 patients (35 CTH, 104 CTH + PF) who were enrolled in the CTH system were audited and added to the CTH-enrolled patients from the ITT sample to provide a total of 479 patients for the CTH per protocol sample to examine the effectiveness of the CTH program (312 SMS education as a comparison group, 40 CTH (35/40, 87.5% additional patients), 127 CTH + PF (104/127, 81.9% additional patients) among enrolled patients. A total of 488 patients enrolled in the CTH system—141 (78 with self-reported diabetes) from CTH practices and 347 (223 with self-reported diabetes) from CTH + PF practices.

Practice and Patient Characteristics

Baseline practice characteristics were very similar across the 3 arms (Tables 2, all $P > .2$). It should be noted that 27 of the 36 practices (9 in each arm) were community health centers. Patient characteristics are also described in Table 3. Most baseline characteristics were similar across study arms. Interestingly, Tables 3 shows that (compared with the respective ITT sample) the CTH + PF per protocol sample had higher levels of renal disease, cardiovascular disease, depression, and baseline BMI, less oral diabetic medicine and more insulin compared with the CTH per protocol sample. Thus, CTH-enrolled patients were more likely to have additional complications or risk factors. In addition, while baseline HbA1c was similar across arms for the ITT analyses (as would be anticipated due to that being one of the balancing criteria used in the randomization), it was higher in the CTH + PF group for the CTH per protocol group. This would indicate that the CTH + PF practices selectively enrolled patients with higher HbA1c levels and possibly more risk factors in CTH.

Clinical Outcomes

Table 4 shows the results of the ITT and CTH per protocol longitudinal analyses of patient-level clinical outcomes over time by study arm, adjusted for patient level covariates in multivariable models. Practice level covariates were not significant and were not included in final models. CTH per protocol analyses compare patients in the CTH and CTH + PF arms who enrolled in the CTH program and were randomly selected for the CTH per protocol sample to all patients in the SMS-ED arm.

HbA1c

Examining slopes (change per year) for each study arm, ITT analyses suggest that patients' HbA1c levels tended to increase over time, but slopes did not differ between study arms (CTH vs SMS-ED, P = .2243; CTH = PF vs SMS-ED, P = .8601) (See Table 4).

However, in the CTH per protocol sample, patients in the CTH + PF arm showed significantly improved HbA1c trajectories over time compared

Table 3. Patient Characteristics (From Chart Audits)

Variable	SMS-ED Arm: Intent to Treat and Per Protocol Samples, Mean (SD) or %	CTH Arm: ITT Sample, Mean (SD) or %	CTH Arm: CTH Per Protocol, Mean (SD) or %	CTH + PF Arm: ITT Sample, Mean (SD) or %	CTH + PF Arm: CTH Per Protocol Sample, Mean (SD) or %
N	312	360	40	385	127
Gender, % female	54.5%	60.6%	62.5%	57.4%	60.6%
Age (years)	58.3 (12.8)	60.0 (12.6)	58.3 (12.5)	60.8 (11.5)	58.3 (11.6)
Number of medical co-morbidities	1.8 (1.1)	1.7 (1.0)	1.4 (0.9)	1.8 (1.0)	1.9 (1.0)
Comorbid conditions					
Hypertension	73.4%	66.1%	65.0%	70.1%	72.4%
Pulmonary	13.1%	10.8%	7.5%	15.3%	15.8%
Diabetic nephropathy	11.5%	12.8%	5.0%	10.7%	10.2%
Renal disease	10.9%	8.1%	5.0%	3.6%	11.8%
Cardiovascular disease	7.4%	6.9%	0.0%	10.9%	11.8%
Depression	18.9%	20.0%	17.5%	19.2%	23.6%
Current smoker	19.6%	14.4%	10.0%	15.1%	13.4%
Baseline HbA1c	8.1 (2.2)	7.9 (2.0)	7.9 (2.0)	7.8 (1.9)	8.5 (1.9)
Baseline body mass index	32.6 (7.6)	32.1 (7.3)	32.4 (5.3)	33.3 (7.2)	34.7 (7.9)
Baseline systolic BP	129.7 (16.1)	130.9 (16.9)	130.9 (17.6)	128.7 (13.5)	129.6 (16.4)
Baseline diastolic BP	76.6 (9.0)	77.6 (9.3)	78.2 (7.8)	76.6 (8.5)	78.9 (9.7)
Medications					
Lipid lowering med	61.4%	65.2%	77.5%	68.5%	71.7%
Antihypertensive	75.2%	74.4%	77.5%	78.9%	78.0%
Antidepressant	21.6%	34.1%	22.5%	36.5%	22.8%
Oral diabetic med	74.3%	81.1%	85.0%	81.3%	72.2%
Insulin	34.3%	33.6%	25.0%	28.6%	41.7%

BP, blood pressure; CTH, Connection to Health; CTH + PF; Connection to Health with practice facilitation; HbA1c, hemoglobin A1c; ITT, intent to treat; PF, practice facilitation; SMS-ED, self-management support education; SD, standard deviation.

Table 4. Intent to Treat and Connection to Health Per Protocol Comparisons of Impact on Hemoglobin A1c over Time

Outcome Is HbA1c Over Time	Intent to Treat, N = 1022		Connection to Health Per Protocol, N = 458	
Variable	Adjusted Models, Coef (SE)	*P*-Value	Adjusted Models, Coef (SE)	*P*-Value
Intercept	7.5385 (0.1941)	<.0001	6.6848 (0.2368)	<.0001
Age group (years)				
17 to 49	Ref	—	Ref	—
50 to 64	0.8017 (0.1368)	<.0001	0.8571 (0.1956)	<.0001
65 or greater	−1.2746(0.1449)	<.0001	−1.057 (0.2199)	<.0001
Female gender	0.0881 (0.1034)	.3942	0.2259 (0.1572)	.1509
BMI (at baseline, centered)	−0.0232(0.0070)	.0010	−0.0436(0.0105)	<.0001
Pulmonary			−0.4775(0.2289)	.0371
Diabetic retinopathy	0.3368 (0.1595)	.0348		
Renal			0.4531 (0.2587)	.0801
Oral diabetic medications	0.7150 (0.1287)	<.0001	0.6452 (0.1817)	.0004
Insulin	1.7418 (0.1117)	<.0001	1.7147 (0.1663)	<.0001
Intervention vs SMS-ED (at baseline)				
CTH vs SMS-ED	−0.0987(0.1551)	.5245	−0.049 (0.3530)	.8891
CTH + PF vs SMS-ED	0.0160 (0.1524)	.9164	0.6519 (0.2300)	.0047
HbA1c change per 12 months (slope)		Compared to SMS−ED		Compared to SMS−ED
SMS-ED	0.1638 (0.0853)	—	0.1546 (0.0920)	—
CTH	0.3022 (0.0756)	.2243	0.0671 (0.2255)	.7193
CTH + PF	0.1441 (0.0721)	.8601	−0.1640(0.1269)	.0422

BMI, body mass index; CTH, Connection to Health; CTH + PF, Connection to Health with practice facilitation; HbA1c, hemoglobin A1c; SMS-ED, self-management support education; SE, standard error.
Overall *P*-value for group x time: 0.2724. The overall group x time effect is used to determine whether there are differences in slopes between the three study arms. The coefficients in the table show the actual slopes (SE) for each study arm, along with the p-value for the differences for CTH vs SMS-ED, and CTH + PF vs SMS-ED.

with patients in the SMS-ED arm (P = .0422). HbA1c (measured as %) trajectories for patients in the CTH arm did not differ significantly from patients in the SMS-ED arm (P = .7193) or between the CTH and CTH + PF arms (P = .3718). On average, HbA1c *increased* by 0.1546% per year in the SMS arm (eg, 8.0% vs 8.1546%) and 0.0671% in the CTH arm (eg, 8.0% vs 8.0671%). In contrast, in the CTH + PF arm, HbA1c *decreased* by 0.1640% per year on average (eg, 8.0% vs 7.836%).

Blood Pressure

Adjusted ITT analysis of systolic blood pressure (BP) suggested that BP remained stable over time in SMS-ED (slope = 0.3474, P = .8248), and BP slopes did not differ by study arm (CTH slope = −1.3276, CTH vs SMS-ED: P = .4383; CTH + PF slope = −0.7788, CTH + PF vs SMS-ED: P = .8380). Results were similar for CTH per protocol analyses examining CTH enrolled patients compared with SMS-ED (SMS-ED slope = −0.1147, P = .8802, CTH slope = 0.5599, CTH vs SMS-ED: P = .7384, CTH + PF slope = −.2733, CTH + PF vs SMS-ED: P = .9042).

BMI

Adjusted ITT analysis of BMI over time indicated a decline in BMI in SMS-ED: (slope = −0.4006, P = .0005), but slopes did not differ for CTH (slope = −0.1554, CTH vs SMS-ED: P = .1173) or CTH + PF (slope = −0.3115, CTH + PF vs SMS-ED: P = .5613). Results were similar in CTH per protocol analyses, with significant decline in BMI in SMS-ED (slope = −0.4014, P < .0001), but similar slopes among study arms (CTH slope = −.2638, CTH vs SMS-ED: P = .6352, CTH +

Table 5. Intent to Treat and Connection to Health Per Protocol Comparisons of Self Management Support Activities over Time

Outcome Is Hemoglobin A1c Over Time	Intent To Treat N = 1054		CTH Per Protocol N = 479	
Variable	Adjusted Models, Coef (SE)	*P*-Value	Adjusted models, Coef (SE)	*P*-Value
Intercept	3.94 (1.32)	—	3.04 (2.87)	—
Age group (years)				
17 to 49	ref	—	Ref	—
50 to 64	0.47 (0.61)	.4463	0.98 (0.94)	.2984
65 or greater	−1.34 (0.66)	.0412	−1.16 (1.04)	.2673
Female gender	.0.39 (0.46)	.4008	1.53 (0.73)	.0376
Depression	3.28 (0.58)	<.0001		
Insulin	3.39 (0.50)	<.0001	5.03 (0.80)	<.0001
Intervention vs SMS-ED (at baseline)				
CTH vs SMS-ED	−0.27 (1.67)	.8705	1.81 (4.73)	.7026
CTH + PF vs SMS-ED	0.81 (1.63)	.6221	4.87 (3.96)	.2192
Pre-post change		Compared to SMS−ED		Compared to SMS−ED
SMS-ED	4.58 (0.72)	—	4.56 (0.84)	—
CTH	6.82 (0.66)	.0223	15.63 (2.32)	<.0001
CTH + PF	7.68 (0.64)	.0013	14.94 (1.30)	<.0001

CTH, Connection to Health, CTH + PF = Connection to Health with practice facilitation; SMS-ED, self-management support education,.

PF: slope = −0.3313, CTH + PF vs SMS-ED: P = .7050).

Process of Care Outcomes

Analysis of total SMS activities during the 18-month pre and post periods are shown in Table 5. Both ITT and CTH per protocol analyses indicated that pre-post change in the number of SMS activities was significantly greater for patients in CTH and CTH + PF study arms, compared with SMS-ED (ITT: CTH vs SMS-ED: 6.82 vs 4.58, P = .0223; CTH + PF vs SMS-ED: 7.68 vs 4.58, P = .0013; CTH per protocol: CTH vs SMS-ED: 15.63 vs 4.56, $P < .0001$, CTH + PF vs SMS-ED: 14.94 vs 4.56, $P < .0001$).

Finally, we examined the potential mediational effects of total number of SMS activities in the CTH per protocol sample on improvement in HbA1c by adding the total number of diabetes-related discussions during the postintervention period to the overall model, along with an interaction term (time × discussions) to adjust for the effect of discussions on change in HbA1c. In this model the difference in slopes for CTH and CTH + PF becomes nonsignificant (CTH vs SMS-ED: P = .9028; CTH + PF vs SMS-ED: P = .2113) and the adjusted slopes increase (SMS-ED: 0.2206, CTH: 0.1905, CTH + PF: 0.0047), suggesting that total SMS activities may partially mediate improvement in HbA1c over time.

Discussion

While patient self management is frequently highlighted as a cornerstone of disease management, steep barriers exist for primary care practices to engage in SMS. This trial of methods for supporting the implementation of SMS for diabetes in primary care practices produced some fascinating results that add to our understanding of how to improve this important practice-level behavior. This real-life study did not require practices in the CTH or CTH + PF arms to enroll patients in CTH, but rather observed practice SMS behaviors and the resulting impacts on patient clinical outcomes as a result of these brief interventions. Relatively few patients were enrolled in CTH, but practices in the CTH + PF arm enrolled more patients and used CTH more effectively as a tool. In particular, they seem to have targeted patients with more risk factors and comorbid conditions and more poorly controlled diabetes for use of CTH. This demonstrates that even a brief practice facilitation intervention can increase the effective uptake of this type of IBCT tool. We believe that a more robust practice facilitation intervention could have resulted in greater and improved use of both SMS and CTH. The relatively small numbers of patients enrolled in CTH limited the ITT impact on HbA1c and other patient outcomes. However, the significant differences seen in the CTH per protocol analyses indicate that where CTH is used with patients with diabetes, it can have a positive impact on patient HbA1c, particularly when coupled with practice facilitation to assist practices with CTH implementation.

Furthermore, both the ITT and CTH per protocol analyses showed a positive increase in the number of SMS activities in the CTH and CTH + PF arms compared with the SMS-ED arm, along with a positive increase in other behavioral health discussions in the CTH and CTH + PF arms in the CTH per protocol analysis. The provision to practices and use of the SMS tools available in CTH significantly improved practices' implementation of SMS activities, and the impact on SMS activities seems to have mediated the impact of the CTH and CTH + PF interventions on HbA1c. It is notable that SMS activities increased more in the 2 CTH arms *even where CTH was not specifically used*. The structured approach to SMS represented in CTH may have provided practices with a model for SMS that they followed even when not using CTH specifically.

Limitations to this study include the disproportionate number of federally qualified health centers in the sample compared with the general practice population of the United States. Engaged practices were from 2 Western states and may not be representative of all practices. Since some of the practices utilized CTH as a method for recording SMS activities and did not capture that data in their electronic health record, the total number of SMS activities may be under-represented in the chart audits, and the overall impact of CTH on SMS activities may be underestimated. In addition, since this was a real life study, practices may have had other initiatives going on that impacted these results.

The results of this study show that an interactive behavior change technology and SMS tool such as CTH can increase aspects of primary care practice SMS activities and improve patient HbA1c levels. This is true despite a relatively low implementation of CTH in the practices. A brief practice facilitation intervention increased effective use of CTH, but more robust practice facilitation may be needed to fully and sustainably implement an IBCT tool of this type. Further studies of approaches for implementing and delivering more efficient and effective SMS for patients with diabetes and other chronic conditions are needed, including how to best target patients for SMS interventions. As alternative, value-based payment models continue to move forward, practices are increasingly motivated to improve patient SMS, and CTH and other IBCT tools can be of assistance if implemented effectively.

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