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

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Abstract

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 three implementation strategies for enhancing SMS for patients with diabetes in 36 primary care practices: 1) SMS education (SMS-ED); 2) SMS education plus CTH availability (CTH); and 3) SMS education, 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 to patients from SMS-ED practices ($p=.0422$). SMS activities were significantly increased in CTH and CTH+PF study arms compared to 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 Connection to Health can increase primary care practice SMS activities and improve patient HbA1c levels. Even brief practice facilitation assists practices in implementing SMS.

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Introduction

Most patients with type 2 diabetes mellitus (T2DM) in the U.S. receive diabetes care in primary care settings. Self-management support (SMS) is a key factor in diabetes care, focusing on the central 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]. Also, few tools are available to assist practices with self-management support.

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 self-management support 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 follow-ups[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 co-morbid 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 Connection to Health 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 RE-AIM framework to guide our evaluation. RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) 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 potentially improve SMS activities, but not substantially; 2) Connection to Health 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

Design

We designed a three-arm, cluster-randomized trial to compare the effectiveness of three 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 HbA1c>9) that might impact the outcomes.

Interventions (see Table 1)

SMS Education (SMS-Ed) Arm:

The SMS-ED arm served as an attention control. Project staff met onsite with practice clinicians and staff members for two one-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 website 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.

Connection to Health (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 on use of CTH. Practices did not, however, receive any practice facilitation to assist with CTH adoption and implementation.

Connection to Health 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 four 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 type 2 diabetes who had received care in each practice for at least one 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 two arms with CTH had patients who were and were not exposed to CTH. To preserve intent-to-treat 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] (i.e. 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 two overlapping patient samples in each practice. The first was a random sample from the population of all patients with type 2 diabetes mellitus who had a HbA1c done during the 18 months prior to the practice baseline date and at least one visit to the practice from baseline to 12 months after baseline, whether or not they participated in CTH – the "Intent to Treat Sample" (ITT). 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 type 2 diabetes mellitus. 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 two samples were not independent of each other; e.g., many in the CTH Per Protocol sample were included randomly in the intent to treat sample.

Measures

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

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 prior to 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 were described and examined as potential confounders and moderators in analyses, including level of quality improvement experience, level of 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, chi-square tests, and one-way ANOVAs were computed for baseline patient and practice characteristics, initially testing for differences between: (1) intervention arms and (2) CTH participants vs. non-participants. 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 chi-square 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 $p < .02$, or differed between treatment arms. Patient-level covariates screened in all analyses included age, gender, BMI, systolic and diastolic blood pressure, comorbid diagnoses (hypertension (HTN), hyperlipidemia, pulmonary, cardiovascular disease, depression, medications [HTN, lipids, oral diabetic, insulin]). We employed methods that utilized all available data, assuming ignorable missingness [56–59]. We used general (or generalized, i.e. 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 two-sided with

alpha=.05 or p values reported. All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, N.C.).

RESULTS

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

Intent-To-Treat 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 intent-to-treat (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 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 three arms (Table 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 2. Most baseline characteristics were similar across study arms. Interestingly, Table 2 shows that (compared to 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 to the CTH per protocol sample. Thus, CTH-enrolled patients were more likely to have additional complications or risk factors. Also, while baseline HbA1c was similar across arms for the intent to treat (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 3 shows the results of the intent-to-treat (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 3).

However, in the CTH per protocol sample, patients in the CTH+PF arm showed significantly improved HbA1c trajectories over time compared to 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 .1546% per year in the SMS arm (e.g. 8.0% vs 8.1546%) and .0671 in the CTH arm (e.g. 8.0% vs 8.0671%). In contrast, in the CTH+PF arm, HbA1c *decreased* by .1640% per year on average (e.g. 8.0% vs 7.836%).

Blood Pressure.

Adjusted ITT analysis of systolic 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 to 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+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 4. 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 to 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 post-intervention period to the overall model, along

with an interaction term (time x 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 non-significant (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 Connection to Health, 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 Connection to Health, but practices in the CTH+PF arm enrolled more patients and used Connection to Health more effectively as a tool. In particular, they appear to have targeted patients with more risk factors and comorbid conditions and more poorly controlled diabetes for use of Connection to Health. 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 Connection to Health limited the ITT impact on HbA1c and other patient outcomes. However, the significant differences seen in the CTH per protocol analyses indicate that where Connection to Health 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 to 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 Connection to Health significantly improved practices' implementation of SMS activities, and the impact on SMS activities appears to have mediated the impact of the CTH and CTH+PF interventions on HbA1c. It is notable that SMS activities increased more in the two 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 to the general practice population of the United States. Engaged practices were from two 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 EHR, 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. Also, 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 Connection to Health 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 self-management support, and Connection to Health and other IBCT tools can be of assistance if implemented effectively.

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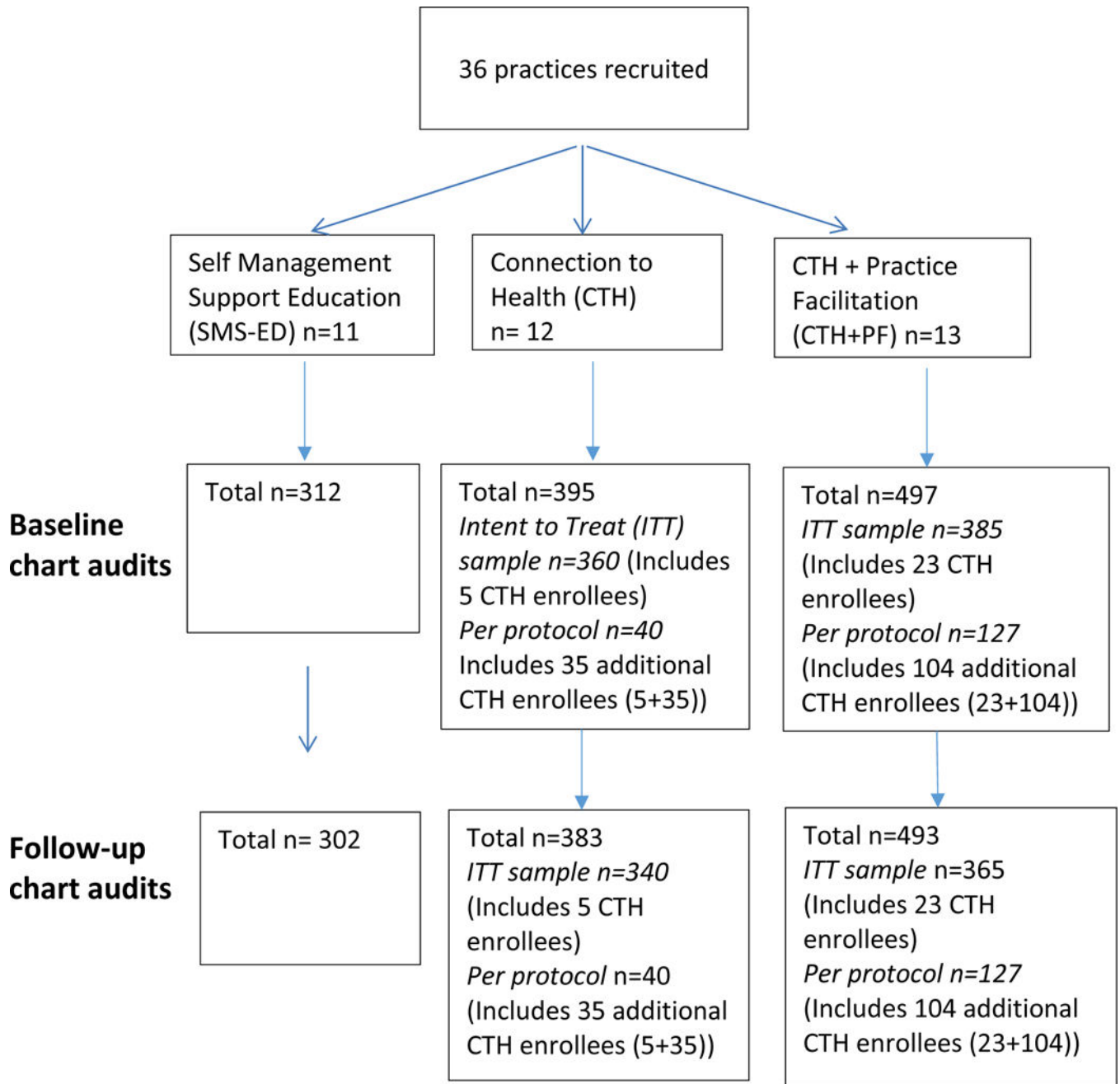


Figure 1.
CONSORT Diagram of Practices and Chart Audits

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
Connection to Health (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 self-management support (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: <ul style="list-style-type: none"> • Improvement team meetings – 4 over approximately 3 mos. • 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 	No	No	Yes

¹ SMS-ED = Self-Management Support Education, CTH = Connection to Health, CTH+PF = Connection to Health with Practice Facilitation

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Table 2.

Baseline Practice and Patient Characteristics

Practice Characteristics	Self Management Support Education (SMS-ED) N=11	Connection to Health (CTH) N=12	Connection to Health + Practice Facilitation (CTH+PF) N=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)		
% Hemoglobin A1c (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 (%) PCMH recognition, n (%)	1 (9.1%) 8 (72.7%)	3 (25.0%) 8 (66.7%)	4 (30.8%) 8 (61.5%)		
Patient Characteristics (From Chart Audits)					
	SMS ED Arm: Intent to Treat and Per Protocol Samples N=312	CTH Arm: Intent to Treat Sample N=360	CTH Arm: CTH Per Protocol Sample N=40	CTH+PF Arm: Intent to Treat Sample N=385	CTH+PF Arm: CTH Per Protocol Sample N=127
Variable	Mean (sd) or %	Mean (sd) or %	Mean (sd) or %	Mean (sd) or %	Mean (sd) or %
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 (.9)	1.8 (1.0)	1.9 (1.0)
Comorbid conditions	73.4%	66.1%	65.0%	70.1%	72.4%
Hypertension	13.1%	10.8%	7.5%	15.3%	15.8%
Pulmonary	11.5%	12.8%	5.0%	10.7%	10.2%
Diabetic nephropathy	10.9%	8.1%	5.0%	3.6%	11.8%
Renal disease	7.4%	6.9%	0.0%	10.9%	11.8%
Cardiovascular disease	18.9%	20.0%	17.5%	19.2%	23.6%
Depression					
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 blood pressure (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	61.4%	65.2%	77.5%	68.5%	71.7%
Lipid lowering med	75.2%	74.4%	77.5%	78.9%	78.0%
Anti-hypertensive	21.6%	34.1%	22.5%	36.5%	22.8%
Anti-depressant	74.3%	81.1%	85.0%	81.3%	72.2%
Oral diabetic med	34.3%	33.6%	25.0%	28.6%	41.7%
Insulin					

¹ SMS-ED = Self-Management Support Education, CTH = Connection to Health, CTH+PF = Connection to Health with Practice Facilitation

Table 3.

Intent to Treat and Connection to Health Per Protocol Comparisons of Impact on Hemoglobin A1c (HbA1c) over Time

Outcome is HbA1c over time	Intent To Treat, N=1022		Connection to Health Per Protocol, N=458	
	Adjusted models Coef (SE)	p-value	Adjusted models Coef (SE)	p-value
Intercept	7.5385 (.1941)	<.0001	6.6848 (.2368)	<.0001
Age group	ref	---	Ref	---
17 to 49	.8017 (.1368)	<.0001	.8571 (.1956)	<.0001
50 to 64	-1.2746 (.1449)	<.0001	-1.057 (.2199)	<.0001
65 or greater				
Gender - Female	.0881 (.1034)	.3942	.2259 (.1572)	.1509
BMI (at baseline, centered)	-.0232 (.0070)	.0010	-0.0436 (.0105)	<.0001
Pulmonary			-.4775 (.2289)	.0371
Diabetic retinopathy	.3368 (.1595)	.0348		
Renal			.4531 (.2587)	.0801
Oral diabetic medications	.7150 (.1287)	<.0001	0.6452 (.1817)	.0004
Insulin	1.7418 (.1117)	<.0001	1.7147 (.1663)	<.0001
Intervention vs SMS-ED (at baseline)	-.0987 (.1551)	.5245	-0.049 (.3530)	.8891
CTH vs SMS-ED	.0160 (.1524)	.9164	0.6519 (.2300)	.0047
CTH + PF vs SMS-ED				
HbA1c change per 12 months (slope)	.1638 (.0853)	Compared to SMS-ED	0.1546 (.0920)	Compared to SMS-ED
SMS-ED	.3022 (.0756)	---	0.0671 (.2255)	---
CTH	.1441 (.0721)	---	-0.1640 (.1269)	---
CTH + PF		.2243		.7193
		.8601		.0422

¹SMS-ED = Self-Management Support Education, CTH = Connection to Health, CTH+PF = Connection to Health with Practice Facilitation

²Overall p-value for group x time: .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.

Table 4.

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	
	Adjusted models Coef (SE)	p-value	Adjusted models Coef (SE)	p-value
Intercept	3.94 (1.32)	----	3.04 (2.87)	----
Age group	ref	---	Ref	---
17 to 49	.47 (.61)	.4463	.98 (.94)	.2984
50 to 64	-1.34 (.66)	.0412	-1.16 (1.04)	.2673
65 or greater				
Gender - Female	. 0.39 (.46)	.4008	1.53 (.73)	.0376
Depression	3.28 (.58)	<.0001		
Insulin	3.39 (.50)	<.0001	5.03 (.80)	<.0001
Intervention vs SMS-ED (at baseline)	-.27 (1.67)	.8705	1.81 (4.73)	.7026
CTH vs SMS-ED	0.81 (1.63)	.6221	4.87 (3.96)	.2192
CTH + PF vs SMS-ED				
Pre-post change	4.58 (.72)	Compared	4.56 (.84)	Compared
SMS-ED	6.82 (.66)	to SMS-ED	15.63 (2.32)	to SMS-ED
CTH	7.68 (.64)	---	14.94 (1.30)	---
CTH + PF		.0223		<.0001
		.0013		<.0001

¹ SMS-ED = Self-Management Support Education, CTH = Connection to Health, CTH+PF = Connection to Health with Practice Facilitation

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