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Original Research

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The impact of enhancing self-management support for diabetes in Community Health Centers through patient engagement and relationship building: a primary care pragmatic cluster-randomized trial

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Abstract

Type 2 diabetes (T2DM) self-management support (SMS) programs can yield improved clinical outcomes but may be limited in application or impact without considering individuals' unique social and personal challenges that may impede successful diabetes outcomes. The current study compares an evidence-based SMS program with an enhanced version that adds a patient engagement protocol, to elicit and address unique patient-level challenges to support improved SMS and diabetes outcomes. Staff from 12 Community Health Center (CHC) clinical sites were trained on and delivered: Connection to Health (CTH; 6 sites), including a health survey and collaborative action planning, or Enhanced Engagement CTH (EE-CTH; 6 sites), including additional relationship building training/support. Impact of CTH and EE-CTH on behavioral self-management, psychological outcomes, and modifiable social risks was examined using general linear mixed effects. Clinics enrolled 734 individuals with T2DM (CTH = 408; EE-CTH = 326). At 6- to 12-month postenrollment, individuals in both programs reported significant improvements in self-management behaviors (sugary beverages, missed medications), psychological outcomes (stress, health-related distress), and social risks (food security, utilities; all $p < .05$). Compared with CTH, individuals in EE-CTH reported greater decreases in high fat foods, salt, stress and health-related distress; and depression symptoms improved within EE-CTH (all $p < .05$). CTH and EE-CTH demonstrated positive behavioral, psychological, and social risk impacts for T2DM in CHCs delivered within existing clinical work flows and a range of clinical roles. Given the greater improvements in psychological outcomes and behavioral self-management in EE-CTH, increased attention to relationship building strategies within SMS programs is warranted.

Keywords: Primary care, Patient engagement, Diabetes, Self-management, Stress, Pragmatic trial

Implications

Practice: Interweaving enhanced patient engagement and relationship building strategies to diabetes self-management support in Community Health Centers is both feasible and impactful.
Policy: Policymakers who want to support and improve diabetes care in Community Health Centers should explore sustainable interventions that include training and supporting relationship building and patient engagement strategies.
Research: Increased attention to relationship building strategies within real-world diabetes interventions is warranted.

Introduction

Thirty million adults are currently diagnosed with type 2 diabetes (T2DM) in the USA and millions more remain undiagnosed [1]. Many of these individuals live and receive medical care in ethnically diverse low-income communities served by our nation's 14,000 Community Health Centers (CHCs). CHCs often have limited resources to provide diabetes self-management support (SMS) [2]. Because up to 95% of the variation in diabetes-related clinical outcomes (e.g., HbA1c) result from patient behaviors that require self-management [3], there is an urgent need to develop, improve, and disseminate effective and sustainable diabetes SMS programs in CHCs.

Broadly defined, SMS refers to the provision of information, skills, and resources necessary for patients to manage their health as effectively as possible through patient-centered and coordinated team care [4]. Existing SMS programs have led to improvements in self-management behaviors (diet,

physical activity, medication taking) [4, 5], clinical indicators (glycemic outcomes, body mass index, cholesterol), and quality of life [5]. However, the vast majority of SMS programs employ a "one size fits all approach" that largely ignores the unique aspects of patient and provider context that drive and maintain disease-related behavior change over time, thus, reducing SMS program effectiveness [6]. The majority of these programs show little evidence of clinical benefit beyond 6 months [4]. Moreover, these programs have generally not been tailored for use by clinical teams in resource-limited settings serving patients confronted by multiple social needs or suffering disproportionately from health inequities [4, 7]. Thus, while existing SMS programs show promise, there remain unanswered questions regarding their usability and general effectiveness in CHCs [4, 8].

Considerable clinical research suggests that the addition of a structured, evidenced-based program of patient engagement, seamlessly infused within SMS behavioral change activities, can maximize the effectiveness of SMS programs for patients with T2DM in primary care [9]. *Patient engagement* is the process by which healthcare teams actively involve and support patients to act on specific behavior change while attending to their personal context, perspective, and beliefs [9, 10]. While the broad umbrella of patient engagement includes multiple strategies, core components include: patient-centered communication that elicits the patient's concerns and experiences and builds trust between the healthcare team and the patient; focus on dynamic and evolving conditions of the patient's environment; and responsiveness to patient's thoughts, emotions, and unique needs around their illness management in ways that drive subsequent behavior change decisions [9, 11]. Examples of current patient engagement strategies include: Autonomy Support [12], Patient Empowerment [9, 11], and Motivational Interviewing [13]. These strategies may be helpful for patients who experience significant barriers to behavioral change (e.g., lower health literacy, poverty, or unique social and emotional challenges) [14]. T2DM treatment programs that have included these patient engagement strategies have demonstrated: increased reach, improved attendance and active programmatic use, greater success in achieving patient behavioral goals, and improved psychosocial outcomes and glycemic control [10, 11, 15] including glycemic outcomes at 1 year [12]. The seamless infusion of a strong and well-structured patient engagement component into SMS, therefore, should maximize long-term SMS effectiveness especially among high risk underserved adults with T2DM. To date, however, there has been no systematic study of the degree to which fully integrating enhanced patient engagement as part of SMS will impact individuals' behavior change over time (e.g., >6 months).

Our research addresses this gap by comparing an evidenced-based electronic SMS behavior change program called Connection to Health (CTH), with an enhanced CTH program that includes a practical patient engagement protocol (Enhanced Engagement CTH [EE-CTH]). In this pragmatic cluster-randomized trial, 12 CHCs clinical sites were randomized and healthcare providers were trained to provide either CTH or EE-CTH to patients as part of their diabetes care primary care appointments. In this report, we focus on patient-reported outcomes that examine program impact on modifiable behavioral and environmental factors linked with diabetes clinical outcomes [16]: behavioral self-management (e.g., diet, physical activity, medication taking), psychological outcomes (health distress, depression symptoms), and actionable social risks (e.g., food insecurity, housing instability). In doing so, we asked two questions: (a) did significant change within each intervention group occur between baseline and 6–12 months follow-up, and (b) was there an added benefit of EE-CTH relative to CTH (differences *between* the intervention groups)?

Research Design and Methods

Sample and recruitment

We conducted a two-arm, pragmatic, cluster-randomized trial to evaluate the added benefit of EE-CTH relative to CTH for patients with T2DM in 12 CHCs. Outcomes (behavior self-management, psychological, social risk) were assessed as part of the program at enrollment and again at 6–12 months from baseline. Clinic randomization was based on health system membership and T2DM panel size using a balancing criterion; with one randomization solution selected at random from the resulting balanced randomization solutions [17]. Twelve clinical sites (6 = CTH; 6 = EE-CTH; Fig. 1) were enrolled from five safety net health systems within the San Francisco Bay Collaborative Research Network (SFBayCRN). These included 10 sites from four federally qualified health centers and two sites from one county health system. Each clinic site was responsible for enrolling a minimum of 62 eligible patients and delivering the protocol to which they were randomized utilizing existing staff and providers, with work flows modified as needed by the clinics to include the program elements. Enrolled patients had to be ≥18 years old, diagnosed with T2DM and receiving care at the clinic for ≥12 months prior to enrollment and able to read in English or Spanish (≥6th grade level). The program was available in English and Spanish. Exclusion criteria were limited to severe mental and/or cognitive disorders. Patient eligibility was verified by clinic electronic medical record data. Clinic staff were given broad latitude over which patients to enroll within these eligibility criteria. All clinics indicated their desire to focus enrollment on patients with an elevated HbA1c (7.5% and higher) while allowing patients with lower HbA1c values to enroll based on staff discretion. Data for this study were collected between 2017 and 2020 and analyzed in 2020 and 2021.

Interventions

Each clinic selected a subset of 2–5 healthcare providers (health educators, nurses, community health workers, medical assistants) to participate in a training program that included an introduction to SMS and a group-based, live tutorial with role play on how to use the program to which their clinic site was randomized. All clinics received implementation support during the patient enrollment period and fidelity was assessed through a checklist at patient/healthcare provider encounters as described in Table 1.

Connection to Health

CTH is a structured, evidence-based, electronic SMS program for T2DM with details available at https://medschool.cuanschutz.edu/connectiontohealth [18, 19]. CTH guides patients and healthcare providers through multiple steps: (a) The person with diabetes (PWD) completes an electronic health survey that assesses areas of self-management and contextual circumstances that may impact self-management (e.g., diet,

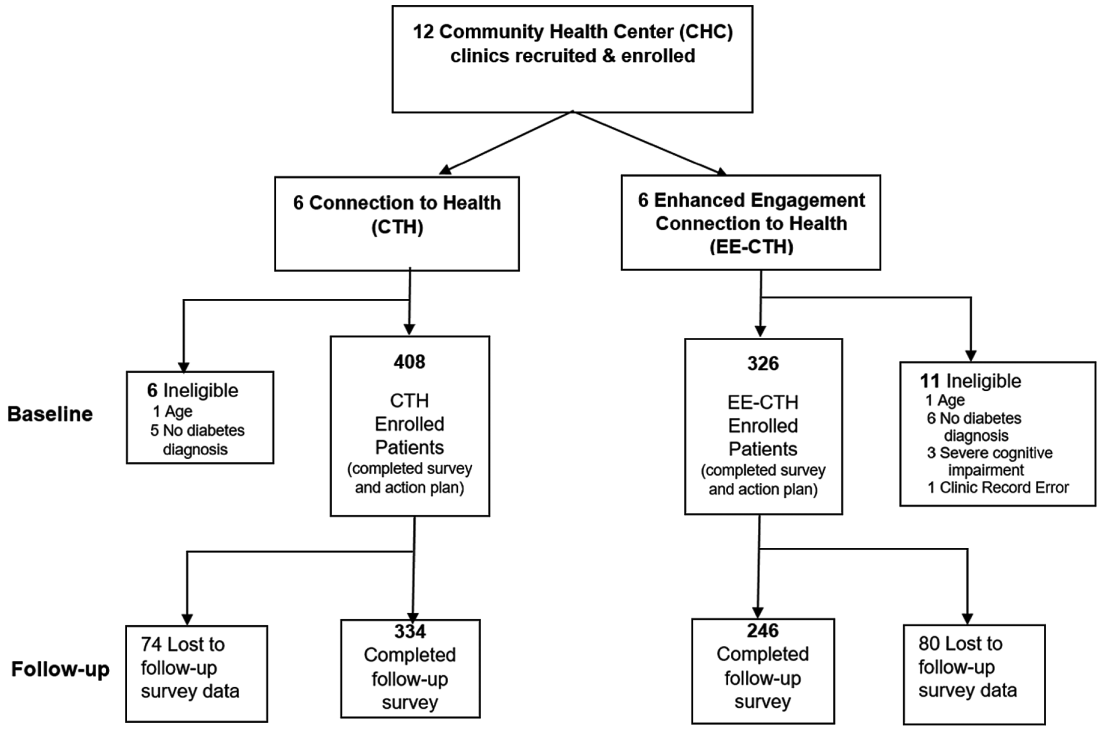

Fig 1 | Consort diagram.

Table 1 | Connection to Health (CTH) and Enhanced Engagement Connection to Health (EE-CTH) program elements

	CTH	EE-CTH
Electronic program element		
• Health assessment of self-management and contextual circumstances with auto-scoring to identify challenges (8–12 min average for completion)	X	X
• Patient prioritizes 1–2 challenges for discussion	X	X
• Patient/healthcare provider structured collaborative goals setting and action plan process (15–25 min average for completion)	X	X (with relationship building prompts)
• Four short (30–90 s) videos to explain the "why" for program elements and anticipatory guidance	—	X
• Administrative site with dashboards to support person-level tracking and panel management	X	X
• Web-based resources for health assessment areas	X	X
Program implementation support		
• Clinic wide orientation meeting	30 min	30 min
• CTH/EE-CTH program training (led by a PhD psychologist and MD primary care physician)	4 hr	4 hr
• Patient engagement and relationship building training (including role plays)	—	2 hr
• Clinic implementation team meetings (including review of workflows, specific patient encounters, and review of program elements)	Four 60 min meetings	Four 60 min meetings
• Observation of patient/healthcare provider program use and debrief with provider by research coordinator (including structured fidelity checklist of CTH/EE-CTH program elements and use of patient engagement and relationship building elements)	≥5/clinic	≥5/clinic
• Additional technical assistance with program	As needed	As needed

medication taking, stress), and identifies possible self-management problems from a list of 15; (b) The PWD prioritizes 1–2 problem areas they want to discuss with their healthcare provider; (c) The healthcare provider reviews the results with the PWD; (d) In collaboration, the PWD and healthcare provider select a goal from a list suggested for the self-management problems or a custom goal and together create a detailed action plan. The electronic action plan is structured

with written prompts and free text space to guide the provider and PWD through systematic action planning including: goal selection, brainstorming actions (what the PWD will do), selecting and creating a detailed plan for one action (when, how often, where), barriers to acting on the plan, and confidence in carrying out the plan [18, 19]. The patient received a printed copy of the health assessment and action plan.

Enhanced-Engagement Connection to Health

Providers in EE-CTH received the same training provided in CTH, plus additional structured training in patient engagement and relationship building skills using Motivational Interviewing, Brief Negotiation, and AASAP strategies [10]. These included two stylistic elements: active listening (paying attention, talking less) and use of open-ended statements; and four content elements: (a) labeling patient feelings and beliefs, (b) use of summarize and reflect statements (e.g., "so you are saying that…"), (c) normalize and accept (e.g., "many of the people I work with feel the same way"), and (d) double reflections to understand and summarize the ambivalence that individuals may experience ("you seem to feel two ways about this: On the one hand…and on the other hand….") [13]. The EE-CTH electronic program emphasized consideration of how the patients' underlying thoughts, feelings, and life context influence their disease management behavior. Building on the CTH program, electronic program elements unique to EE-CTH were: (a) four PWD facing (30–90 s) videos that emphasized the "why" of the program elements (e.g., why is your healthcare provider asking you these questions) and anticipatory guidance statements to prepare PWD for how they may feel (e.g., you may feel disappointed or frustrated when you see your health assessment results) [10, 13], and (b) an alternative action plan sequence that prompts and supports healthcare professional use of relationship building strategies.

The protocol was approved by the UCSF Institutional Review Board.

Measures

CTH and EE-CTH included identical measures that provided a comprehensive assessment of relevant and actionable problem areas related to diabetes management and clinical outcomes.

Behavioral self-management measures

Multiple single item assessments of healthy diet including: number of daily servings of vegetables, days in the last week eat high fat/food from fast food restaurants, daily sugar sweetened beverages, and salt (≤2 days/week eating processed/canned foods and no extra salt added to food vs. > 2 days/week processed/canned food and/or extra salt added to food at meals) [20, 21]. Self-management behaviors additionally included: physical activity (≥150 vs. <150 min weekly based on reported average frequency and duration of weekly moderate to strenuous physical activity) [22], missed medications in past 7 days (0–7) [23, 24], current tobacco use (no/yes), and number of alcoholic drinks in the past week [25, 26].

Psychological and stress measures

Health-related distress was assessed with two items based on the Diabetes Distress Scale (DDS2) [27] and examined continuously (1–5) and using an established threshold 1–1.99 = no/low distress, 2–2.99 = moderate distress, ≥3.00 = high distress; ≥2.00 = elevated distress). General elevated stress from a recent major life event was assessed with one item (no/yes) [28]. Depression symptoms were assessed with the (Patient Health Questionnaire [PHQ]) PHQ2/PHQ8 following positive PHQ2 screens and trichotomized as: negative screen/PHQ8 0–9 = no/low, 10–14 = moderate, and ≥15 significantly elevated depression symptoms [29].

Motivation

The 9-item Motivation and Attitude Toward Changing Health [30] (MATCH) assesses motivational factors around making and/or maintaining a behavioral change (1 = "strongly disagree" to 5 = "strongly agree").

Social risks

Measured by four items (yes/no) to assess current experience: (a) "Running out of food before having enough money or food stamps to buy more", (b) "Problems paying bills, like electric, gas, water, or phone bills", (c) "Not having enough money to pay for bus fare or access to reliable transportation to medical appointments", and (d) "Unstable housing including eviction, foreclosure, homelessness or staying with friends/family" [31].

Patient demographics (age, self-identified gender, race, education level) were captured to describe the sample.

Data analysis

χ^2 or Student t tests, as appropriate, compared CTH and EE-CTH on participant characteristics and baseline values of outcome variables. These analyses were repeated to test for differences between participants with missing vs. complete follow-up data. Sample size and power estimates are based on two-sided $\alpha = 0.05$ and between intervention group tests at follow-up. Assuming an Intraclass Correlation Coefficient of ≤1% and estimating a 20% attrition rate, a postattrition sample of 600 allows for detection of a small/medium standardized effect size ($d = 0.29$ SD unit differences). General linear mixed effects models, adjusting for repeated observations on individuals and clustering of individuals within clinics were used to analyze continuous or semicontinuous outcomes. Generalized estimating equations approaches were used for repeated measures dichotomous outcomes. Covariates associated with treatment arm or missingness were included in the analyses. In a sensitivity analysis we limited the follow-up responses to those captured within the strict protocol time limits of 6–12 months after the first assessment. Hypothesis tests were two sided with $\alpha = 0.05$ or p values reported. All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC) [32].

Results

The CONSORT diagram is presented in Fig. 1. Baseline clinic characteristics were similar across the CTH and EE-CTH clinics regarding size (mean 1,198 ± 1,586 and 1,148 ± 1,079 total patients seen per week), number of patients with T2DM (mean 1,965 ± 2,500 and 2,192 ± 2,466), and % of patients with HbA1c > 9.0 (21.2% vs. 26.6%). Over two-thirds of patients were receiving Medical or Medicare insurance (76.7% vs. 69.9%).

CTH clinics enrolled a combined 408 eligible patients and 326 individuals were enrolled by EE-CTH clinics (total sample n = 734). The patient sample mean (*SD*) age was 54.0 years (11.8), 59.5% self-identified as female, 72.2% self-identified as Latino, and 59.5% completed high school or greater education. Individuals in the CTH and EE-CTH did not differ at baseline on demographic nor health assessment measures, with the exception that EE-CTH participants reported greater stress, both generally and around their health, more likely to be current smokers, and eating more high fat foods than CTH participants (all $p < .05$, Table 2). Length of time between enrollment and follow-up assessment was on average 9.05 (2.35) months in the CTH group and 8.62 (2.38) in EE-CTH. Attrition rates at follow-up did not differ by group (18.1% CTH, 24.5% EE-CTH, Fig. 1); greater attrition in both groups was associated with participants who did not identify as Latino, obtained higher education, or reported unstable housing or transportation problems ($p < .05$). All models were adjusted for race, ethnicity, gender, and education.

Changes in behavioral self-management

At enrollment, self-management challenges were common (Table 3). For example, 57% of all participants reported daily consumption of sugar sweetened beverages (e.g., soda), on average participants reported missing taking medications 1.7 days a week, and 71% reported engaging in fewer than the nationally recommended 150 min of physical activity a week. At follow-up, statistically significant improvements were found in four of the eight measures of behavioral self-management in the EE-CTH group including: significant reductions in high fat foods, salt and sugar sweetened beverages, and fewer missed medication days (Table 3). In the CTH group, significant improvements were reported in the two areas of sugar sweetened beverage consumption and missed medication days (Table 3). Directly compared with individuals in the CTH condition, those in the EE-CTH condition reported significantly larger improvements in diet, seen in both larger decreases in high fat food and salt in their diet (Table 3). There was no significant change in vegetable consumption, alcohol or smoking in either intervention group or other differences between groups over time.

Changes in psychological outcomes and motivation

Psychological strain at enrollment was common in both groups; overall 17% reported elevated depression symptoms (≥10 on PHQ), 41% reported general life stress, and 63% reported elevated health-related distress (CTH = 56% and EE-CTH = 69% reaching the threshold for elevated distress ≥2.00). At follow-up, significant improvements were seen in all three psychological measures within the EE-CTH group, while improvements in general life stress and health distress but not depression symptoms were seen in the CTH group (Table 3). Compared with CTH, EE-CTH participants were more likely to report greater reductions in general life stress and health distress (Table 3). Strikingly, 55% of EE-CTH participants who reported elevated health distress at enrollment no longer reported elevated distress at follow-up, compared with 41% in the CTH group (p = .006). Self-reported motivation levels started moderately high (approximately 4 on a 1–5 scale) for both groups and did not significantly change.

Changes in actionable social risks

At enrollment, 39% of the sample in both groups reported experiencing one or more of the four actionable social risks assessed. For individuals experiencing social risks, CTH and EE-CTH action planning could include referrals and navigation assistance within the clinic (e.g., clinic food pantry, social worker) and/or community resources (e.g., community food bank) to address social risks. At follow-up statistically significant decreases in the frequency of food insecurity and concerns paying utilities/bills were reported in both the CTH and EE-CTH groups (Table 3). There were no significant differences in the degree of improvement between groups nor a change in rates of reported housing instability or transportation challenges in either group over time (Table 3).

Additional sensitivity analyses were undertaken to repeat the analyses in Table 3 limiting follow-up assessments to those completed during the strict 6- to 12-month follow-up period. Results of sensitivity analyses yielded a similar pattern of findings.

Discussion

Among adults with T2DM receiving care in CHC primary care settings, we examined the impact of two SMS programs and tested the added utility of an enhanced patient engagement program (EE-CTH) relative to a strictly behaviorally focused SMS program (CTH). Our results indicate multiple positive behavioral, psychological, and social impacts of both programs 6–12 months following initial assessment and action planning. On average, individuals exposed to the both programs reported significant improvements in: drinking fewer sugar sweetened beverages, fewer missed medication days, lower general life stress and health-related distress, food security, and paying for utilities or other bills. In contrast, compared with individuals in CTH, those in EE-CTH reported larger decreases in high fat foods and salt in their diet, and larger reductions in general life stress and health-related distress. Notably, significant improvements in depression symptoms were reported in EE-CTH only. These results build on extant literature that supports the utility and impact of SMS programs in primary care [18, 33] and SMS diabetes programs delivered by community health workers [34, 35], and extend these findings to suggest that interweaving enhanced patient engagement strategies in CHC clinical environments is impactful.

Major improvements in participant-reported psychological well-being occur, including a reduction in health-related distress. Within group changes and between group differences in health-related distress are clinically and statistically meaningful, exceeding the minimal clinically important difference [36] of ≥0.21. Health-related distress for individuals with diabetes or diabetes distress is linked with clinical outcomes (e.g., HbA1c) and has been increasingly recognized as an important stand-alone outcome [37]. While multiple psychological and behavioral intervention studies have now documented distress reductions in controlled studies, very few have been delivered within the real world of primary care and by clinic staff across a range of roles.

In both CTH and EE-CTH, we observe significant reductions in the two most frequently endorsed actionable social risks: food insecurity and ability to pay bills. The magnitude of change for these social risks is in line with outcomes from

Table 2 | Description of participants by intervention group at baseline (CTH and EE-CTH)

Measure	CTH (*N* = 408)		EE-CTH (*N* = 326)		*p*
	Mean or *n*	*SD* or %	Mean or *n*	*SD* or %	
Gender, % female	240	58.8%	197	60.4%	.66
Age (years)	54.0	11.8	54.1	11.9	.89
Race and ethnicity					
Latino	304	74.5%	226	69.3%	.182
White	150	36.8%	112	34.4%	.524
Black or African American	31	7.6%	39	12.0%	.093
Asian	19	4.7%	27	8.3%	.09
Native Hawaiian or other Pacific Islander	11	2.7%	5	1.5%	.376
Native American or Alaska Native	9	2.2%	12	3.7%	.332
Some other race	209	51.2%	145	44.5%	.121
Education					.552
Less than high school	173	42.4%	123	37.7%	
High school or GED	118	28.9%	101	31.0%	
Some college	73	17.9%	64	19.6%	
College graduate	32	7.8%	33	10.1%	
Master's or professional degree	10	2.5%	5	1.5%	
Doctoral degree	1	0.2%	0	0.0%	
Vegetable serving (daily)	2.9	2.0	2.7	1.8	.207
High fat foods (days per week)	2.0	1.8	2.4	1.6	.005
High salt use	79	19.4%	83	25.5%	.098
Sugary drinks					.244
None	184	45.1%	130	39.9%	
1 per day	101	24.8%	97	29.8%	
2 per day	61	15.0%	46	14.1%	
3 or more per day	62	15.2%	51	16.6%	
Physical activity					.129
≥150 min	131	32.1%	85	26.1%	
100–149 min	30	7.4%	34	10.4%	
<100 min	247	60.5%	206	63.2%	
General life stress, % yes	173	42.4%	166	40.7%	.047
Health distress (mean, *SD*)	1.17	1.11	1.38	1.07	.01
Health distress					.001
No/low distress (≤1.99)	176	43.1%	97	29.8%	
Moderate distress (2–2.99)	109	26.7%	115	35.3%	
High distress (≥3)	123	30.1%	114	35.0%	
Depression symptoms					.317
No/low depression symptoms (≤ 9)	350	85.8%	268	82.2%	
Moderate depression symptoms (10–14)	27	6.6%	31	9.5%	
High depression symptoms (≥15)	31	7.6%	27	8.3%	
Missed medication days	1.8	3.5	1.7	3.2	.576
Alcohol use frequency	0.8	2.4	0.6	1.9	.301
Smoking, % yes	41	10.0%	41	12.6%	.011
MATCH motivation level (1–5)	4.01	0.56	4.00	0.52	.88
Food insecurity, % yes	74	18.1%	71	21.8%	.336
Housing instability, % yes	40	19.8%	30	9.2%	.951
Utility/other bills, % yes	114	27.9%	87	26.7%	.921
Transportation, % yes	53	13.0%	46	14.1%	.894

other intervention programs that have exclusively targeted social risk reduction suggesting the integration of social risks within a broader SMS program can be effective [31]. Reductions in risks related to housing and transportation, however, were minimal, which may reflect the relative lack of within clinic and/or community resources that were available to patients in geographic locations of the study. There were no between group differences in these findings. It may be that staff screen for and intervene on social risks to the extent possible, leading to minimal additional impact of the EE-CTH prompts and support. As CHCs increasingly screen for and seek to address actionable social risks within their workflows

Table 3 | Change in behavioral self-management, psychological, motivation, and social risk variables by intervention group (CTH and EE-CTH) from enrollment to follow-up

Measure	Scale	Adjusted estimates		CTH Δ value, *p* value	EE-CTH Δ value, *p* value	Δ CTH vs. EE-CTH (time × intervention), *p* value
		CTH Est (SE)	EE-CTH Est (SE)			
Vegetable serving[b] (daily)	0–7					
Baseline		2.96 (0.27)	2.79 (0.28)	+0.21	0.00	+0.21
Follow-up		3.17 (0.28)	2.79 (0.27)	*p* = .1738	*p* = .9202	*p* = .3121
High fat foods[b] (days/week)	0–7					
Baseline		2.16 (0.15)	2.50 (0.15)	−0.05	−0.54	−0.49
Follow-up		2.11 (0.15)	1.96 (0.16)	*p* = .6604	*p* < .0001	*p* = .0090
Salt[a]	0 = no concern; 1 = concern					
Baseline		19.6% (2.1)	25.7% (2.6)	+2.6%	−7.5%	−10.1%
Follow-up		22.2% (2.4)	18.2% (2.7)	*p* = .2887	*p* = .0459	*p* = .0336
Sugary drinks (daily)	0, 1, 2, 3+					
Baseline		0.95 (0.11)	0.96 (0.11)	−0.24	−0.32	−0.08
Follow-up		0.71 (0.11)	0.64 (0.12)	*p* = .0019	*p* < .0001	*p* = .5069
Physical activity (min daily)	1 < 100, 2 = 100–150, 3 ≥ 150					
Baseline		2.26 (0.07)	2.35 (0.07)	−0.13	−0.01	−0.12
Follow-up		2.13 (0.07)	2.34 (0.08)	*p* = .0583	*p* = .8425	*p* = .2471
Missed medication days	0–7					
Baseline		1.76 (0.18)	1.59 (0.20)	−0.55	−0.98	−0.43
Follow-up		1.21 (0.20)	0.61 (0.23)	*p* = .0296	*p* < .0001	*p* = .2109
Alcohol use frequency	Continuous					
Baseline		0.80 (0.14)	0.66 (0.15)	−0.23	−0.21	−0.02
Follow-up		0.57 (0.15)	0.45 (0.16)	*p* = .1495	*p* = .1071	*p* = .9240
Currently smoking[a]	Binary					
Baseline		0.09 (0.02)	0.11 (0.02)	−1.4%	−3.3%	−1.9%
Follow-up		0.07 (0.02)	0.08 (0.02)	*p* = .5037	*p* = .1604	*p* = .5981
General life stress[a]	Binary					
Baseline		0.44 (0.03)	0.53 (0.03)	−7.9%	−18.9%	−11.0%
Follow-up		0.36 (0.03)	0.34 (0.03)	*p* = .0355	*p* < .0001	0.0648
Health distress	1–5					
Baseline		2.22 (0.06)	2.42 (0.07)	−0.28	−0.62	−0.34
Follow-up		1.94 (0.07)	1.80 (0.08)	*p* = .0002	*p* < .0001	*p* = .0017
Depression symptoms (PHQ)	1 = 0–9; 2 = 10–14; 3 = 15+					
Baseline		1.24 (0.04)	1.29 (0.04)	−0.05	−0.11	−0.06
Follow-up		1.19 (0.04)	1.18 (0.04)	*p* = .1879	*p* = .0122	*p* = .3538
MATCH motivation level	1–5					
Baseline		4.02 (0.08)	4.01 (0.09)	+0.06	−0.01	+0.05
Follow-up		4.08 (0.08)	4.00 (0.09)	*p* = .1300	*p* = .8271	*p* =.2584
Food insecurity[a]	Binary					
Baseline		0.18 (0.02)	0.21 (0.02)	−6.5%	−7.4%	−0.9%
Follow-up		0.11 (0.02)	0.14 (0.02)	*p* = .0079	*p* = .0373	*p* = .9090

Table 3. Continued

Measure	Scale	Adjusted estimates		CTH Δ value, *p* value	EE-CTH Δ value, *p* value	Δ CTH vs. EE-CTH (time × intervention), *p* value
		CTH Est (SE)	EE-CTH Est (SE)			
Housing instability[a]	Binary					
Baseline		0.10 (0.02)	0.09 (0.02)	−0.6%	0.4%	1.0%
Follow-up		0.09 (0.02)	0.09 (0.02)	*p* = .7713	*p* = .8656	*p* = .9280
Utility/other bills concern[a]	Binary					
Baseline		0.28 (0.02)	0.27 (0.03)	−8.5%	−7.7%	−0.8%
Follow-up		0.19 (0.02)	0.19 (0.03)	*p* = .0072	*p* = .0362	*p* = .9332
Transportation concern[a]	Binary					
Baseline		0.12 (0.02)	0.14 (0.02)	−1.0%	−0.05%	−0.5%
Follow-up		0.11 (0.02)	0.13 (0.02)	*p* = .6572	*p* = .8611	*p* = .9927

[a]Measures utilized Genmod with random effect removed (given clinic nonsignificant).
[b]Measures utilized Proc Mixed (general linear mixed models) with a random effect for patient and clinic for all continuous (or semicontinuous) variables.

and across different roles, it will be important to continue to understand the impact of blended intervention and engagement approaches and to further test how social risk screening can be more fully integrated into more comprehensive management programs.

Although two of the most common behavioral self-management challenges at initial assessment are servings of vegetables and physical activity, and a majority of action plans focus in these areas [19], we do not find improvements in either intervention group over time. It may also be that these are topics that PWDs are already accustomed to working on with their healthcare teams [19], and that action plans on these topics have limited additional utility for such individuals. Likewise, we do not observe changes in smoking and alcohol overuse, suggesting that individuals with concerns in these areas may benefit from more specifically targeted or intensive care programs.

Taken together, the pattern of findings has several implications for diabetes care in CHCs. First, programs such as CTH and EE-CTH are feasible to implement and appear to add benefit to existing diabetes primary care services. Second, the added utility of EE-CTH relative to CTH provides further support for utilizing brief, practical, evidence-based relationship building strategies. The additional improvements found in the EE-CTH group suggest that these relationship building strategies can be easily learned and provided by nonmental health professionals, making the program adaptable to different clinical workflows and roles.

This pragmatic study has several strengths: a cluster-randomized comparative design; an evidence-based intervention; delivery within existing CHC workflows across a variety of roles; and inclusion of a large community sample. However, several limitations are important to keep in mind. First, the study included a comparative effectiveness design and did not allow for comparison to usual care. This was unavoidable because assessing for these areas without offering assistance in a clinical care context raises ethnical concerns. Second, because assessment was limited to only two time points, some change was likely not documented and like any intervention in a real-world context, other factors (e.g., clinic led initiatives) could have limited or enhanced change. The electronic program did not capture the language (English vs. Spanish) the survey or action plan was viewed, which precluded analyses examining language. Finally, the current report relies on self-reported data and will be strengthened by other data sources (e.g., clinical data from Electronic Health Record) in the future.

In conclusion, both the CTH and EE-CTH programs demonstrated positive impacts for individuals with T2DM cared for in resource-limited clinical settings serving patients struggling disproportionately from social needs and health inequities. EE-CTH, focused on relationship building and was easily learned and adopted by health workers, and led to significantly greater reductions in psychological stress/distress and aspects of behavioral self-management relative to CTH. Greater attention to relationship building strategies within the context of self-management improvement programs and CHCs is warranted.

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Compliance with Ethical Standards

Conflict of Interest: All authors declare that they have no conflicts of interests. Lawrence Fisher is a consultant or advisory

board member with Elli Lilly, Abbott Diabetes Care, Asencia, and Dexcom.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent: All study activities were reviewed and approved by the University of California—San Francisco Institutional Review Board. Only deidentified data were collected for study purposes, therefore informed consent was not required.

Welfare of Animals: This article does not contain any studies with animals performed by any of the authors.

Data Availability

The study was preregistered at ClinicalTrials.gov, identifier NCT02834923. Deidentified data and analytic code used to conduct study analyses are not publicly available. All such data, code, and materials will be made available by emailing the corresponding author.

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