Effect of Problem-Solving-Based Diabetes Self-Management Training on Diabetes Control in a Low Income Patient Sample

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BACKGROUND: Lower socioeconomic status is associated with excess disease burden from diabetes. Diabetes self-management support interventions are needed that are effective in engaging lower income patients, addressing competing life priorities and barriers to self-care, and facilitating behavior change.

OBJECTIVE: To pilot test feasibility, acceptability, and effect on disease control of a problem-based diabetes self-management training adapted for low literacy and accessibility.

DESIGN: Two-arm randomized controlled trial powered to detect a 0.50% change in A1C at follow-up with a 2-sided alpha of 0.05 in a pooled analysis.

PARTICIPANTS: Fifty-six urban African-American patients with type 2 diabetes and suboptimal blood sugar, blood pressure, or cholesterol control recruited from a diabetes registry within a university-affiliated managed care organization.

INTERVENTIONS: A group, problem-based diabetes self-management training designed for delivery in an intensive and a condensed program format. Three intensive and three condensed program groups were conducted during the trial.

MAIN MEASURES: Clinical (A1C, systolic blood pressure [SBP], diastolic blood pressure [DBP], LDL and HDL cholesterol) and behavioral (knowledge, problem solving, self-management behavior) data were measured at baseline, post-intervention, and 3 months post-intervention (corresponding with 6–9 months following baseline).

RESULTS: Adoption of both programs was high (>85% attendance rates, 95% retention). At 3 months post-intervention, the between-group difference in A1C change was -0.72% ($p=0.02$), in favor of the intensive program. A1C reduction was partially mediated by problem-solving skill at follow-up ($\beta = -0.13$, $p=0.04$). Intensive program patients demonstrated within-

group improvements in knowledge ($p<0.001$), problem-solving ($p=0.01$), and self-management behaviors ($p=0.04$). Among the subsets of patients with suboptimal blood pressure or lipids at baseline, the intensive program yielded clinically significant individual improvements in SBP, DBP, and LDL cholesterol. Patient satisfaction and usability ratings were high for both programs.

CONCLUSIONS: A literacy-adapted, intensive, problem-solving-based diabetes self-management training was effective for key clinical and behavioral outcomes in a lower income patient sample.

KEY WORDS: diabetes; self-management; problem-solving; training.
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Lower socioeconomic status (SES) groups in the U.S. suffer excess disease burden from type 2 diabetes.^{1,2} This excess burden is mediated by risk factors such as hyperglycemia, hypertension, and dyslipidemia, which are modifiable with medical management and lifestyle changes. Patient diabetes education is recommended to facilitate patient self-management of these risk factors.³ However, multiple competing life priorities, socioeconomic problems (money, housing, street crime), and familial problems (family, caretaker responsibilities) serve as barriers to diabetes self-care.⁴ To achieve the chronic care model goal of informed, activated patients engaged in disease self-management,⁵ diabetes self-management support programs are needed that are effective in engaging vulnerable populations, addressing competing priorities as well as educational needs, and facilitating behavior change. Moreover, such programs must be effective in overcoming barriers such as low literacy.⁶

This study aimed to: 1) design a problem-solving-skill based diabetes self-management intervention in intensive and condensed delivery formats and adapted for low literacy, and 2) conduct a small, randomized controlled trial to test the feasibility, accessibility and effectiveness of the intensive and condensed programs in a sample of lower SES, type 2 diabetes patients in suboptimal diabetes control.

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RESEARCH DESIGN AND METHOD

Intervention Development

Project DECIDE (Decision-making Education for Choices In Diabetes Everyday), was based on a problem-solving model of chronic disease self-management.⁷ Problem solving, which has its origins in the behavioral and cognitive basic sciences, is an identified behavior change technique.⁸ As a core self-management behavior in the American Association of Diabetes Educators' AADE 7 framework, problem solving is conceptualized as intervening on barriers to self-care and enabling patients to carry out all other behaviors.^{9,10}

Problem-Solving Training The D'Zurilla and Nezu problem-solving therapy (PST)¹¹ was the model for the training. The Project DECIDE training is a diabetes-adapted version of this standard PST,¹² developed in a traditional format (eight sessions of health problem-solving training) and a condensed format (one session of health problem-solving training). Each training was conducted with an accompanying patient workbook entitled, *Hitting the Targets for Diabetes and Your Heart: Your Problem-Solving Workbook*. See [Online Appendix](#) for an intervention overview with module descriptions.

Diabetes and CVD Education Module Prior to the problem-solving training, all participants completed a prerequisite, single-session education module with an accompanying *Diabetes and Your Heart Facts & Information Patient Workbook*. The module targeted awareness of CVD risk factors; knowledge of clinical targets for A1C, blood pressure, and cholesterol; and self-management behaviors of taking medication, self-monitoring, healthy eating, and getting regular physical activity. Further details of the educational content are described elsewhere.^{13,14} The interventions and materials were adapted for low literacy and accessibility using available guidelines.¹⁵⁻¹⁸ Patient workbooks also utilized colors (red/green) and symbols (thumbs up/thumbs down) for key concepts. Pre-testing demonstrated module effectiveness and suitability for persons with low and average literacy¹³ and for persons with mild to moderate visual and cognitive impairments.¹⁴

Pilot Intervention Trial

The study was approved by the Institutional Review Board. All participants gave signed informed consent.

Participant Recruitment. The recruitment sample was identified from a diabetes registry compiled from an administrative database of a university-affiliated managed care organization in Baltimore, Maryland. The registry included patients from community practice sites in medically underserved areas of Baltimore City used for recruitment in the current study. Registry eligibility criteria were age 25 years or older, African American by self-report, diagnosed with diabetes (ICD 250), and not actively participating in the managed care organization's disease management programs. To recruit from this registry, an invitation letter with refusal postcard was

mailed. Following the mailing, a research assistant made a telephone call to all persons who did not return the refusal postcard. Interested persons who met the initial inclusion criteria were scheduled to attend a baseline visit.

Procedure During the baseline visit, after informed consent, study questionnaires were administered in interview format. Laboratory and physical measures were taken to screen for the clinical eligibility criteria of suboptimal disease control in one or more of the following: blood sugar (A1C >7.0%), blood pressure (systolic blood pressure >130 mmHg or diastolic blood pressure >80 mmHg), or lipids (LDL cholesterol >100 mg/dl or HDL cholesterol <50 mg/dl).¹⁹ The following were the exclusion criteria: mentally incompetent or unable to complete assessment (interview, tests, venipuncture), transportation or medical issues rendering person unable to attend visits, comorbid conditions likely to lead to death in the subsequent 3-4 years of the study (e.g. cancer, AIDS, end-stage renal disease, active tuberculosis, Alzheimer's disease), and plans to relocate during the period of the study.

Eligible participants were randomized to the intensive (one diabetes and CVD education session and eight problem-solving training sessions) or the condensed (one Diabetes and DVD education session and one problem-solving training session) program. Both programs were delivered as bi-weekly groups, with 8-10 participants per group. For standardization, interventionists underwent training and followed prepared manuals for each intervention. For quality assurance, all sessions were audiotaped, and randomly selected audiotapes were reviewed.

Assessments were performed at three time points: baseline, 1-week post-intervention for selected behavioral measures, and 3 months following termination of each intervention (3-month post-intervention follow-up) for behavioral and clinical outcomes. The 3-month post-intervention follow-up assessment corresponded to 6-9 months following baseline.

Measures

Sociodemographic and Medical History. Sociodemographic data and medical history were collected by clinical interview. Participants were requested to bring their medications with them to their data collection visits, at which time the medications were recorded by the data collector. Literacy was measured using the Wide Range Achievement Test (WRAT-3).²⁰ Depression was measured using the Beck Depression Inventory Fast Screen for Medical Patients.²¹

Clinical Measures. A1C was measured using high-pressure liquid chromatography. LDL and HDL were measured using standard techniques. Blood pressure was assessed using a random-zero sphygmomanometer; the mean of three readings at one visit was used at baseline and again at follow-up.

Diabetes and CVD Knowledge Test. ¹³ and ¹⁴ are a 14-item scale based on information important for diabetes self-management from the ADA clinical practice recommendations.¹⁸ Items assess awareness of risk for CVD in persons with diabetes; awareness of "bad" and "good" cholesterol; clinical targets for fasting blood glucose, A1C, blood pressure, LDL and HDL cholesterol; and knowledge of self-management areas of blood glucose self-

monitoring, nutrition, and physical activity. Correct responses are each worth 1 point; total scores range from 0 to 14.

Health Problem-Solving Scale (HPSS).²² is a 50-item scale designed to assess positive/effective and negative/ineffective aspects of health-related problem solving across the domains of problem orientation/motivation, problem-solving skill, and transfer of past experience/learning. Participants respond on a 5-point Likert scale ranging from (0-Not at all true of me, to 4-Extremely true of me). Total scores are derived from summing positive/effective items in each domain and summing reverse-scored negative/ineffective items in each domain. Higher scores indicate more effective problem solving. Reference score ranges for total HPSS from two initial development samples are available, along with A1C values associated with each quartile range of HPSS scores in the clinic-based diabetes sample.²²

Summary of Diabetes Self-Care Activities scale (SDSCA).²³ is a well-established measure of frequency of self-care behaviors and regimen adherence. The 11 core items assessing diet, exercise, glucose testing, foot care, and smoking were used, as well as the additional items provided for specific diet, foot care, and medication taking. Possible total scores for the scale ranged 0 (low self-care/adherence) to 78 (high self-care/adherence).

Barriers. Problems with self-management were assessed with the following item from the Michigan Diabetes Training and Research Center Diabetes History Questionnaire (Available at <http://www.med.umich.edu/mdrtc/profs/survey.html>): "What are the three most difficult problems you face in caring for your diabetes? Try to be as specific as possible." We added the following question to each identified barrier: "How difficult has [problem] been for you over the past month?" Participants rated each problem on a scale from 1 (not difficult) to 10 (extremely difficult).

Patient Satisfaction and Usability. Patient satisfaction and usability were assessed using a series of nine items on which participants rate, on a scale from 1 (least) to 5 (most), ease of use, ease of understanding, usability, helpfulness, and satisfaction with the education program and workbooks.^{13,14}

Data Analysis

Categorical variables were described using frequency distributions, and continuous variables were described using mean and standard deviation, for the entire study sample and by intervention assignment. Distributional differences in these variables between intervention groups were evaluated using chi-square test for categorical variables and analysis of variance for continuous variables.

A total sample size of 50 for the pilot study was based on 90% power to detect a clinically meaningful change of 0.5% in the primary outcome, A1C, at 3 months post-intervention with a 2-sided alpha of 0.05 in a pooled analysis. Intervention effects were evaluated based on the intent-to-treat (ITT) principle. Available data from every participant who was randomized were included in the ITT analysis using mixed-

effects models. Visit-specific means for each group were characterized in the primary mean model through the inclusion of visit specific indicators, intervention group indicator, and the interaction terms between the visit and group indicators. Unstructured covariance was used for the covariance model, and robust standard error estimates were used for statistical inferences.

A series of linear regression analyses were conducted to explore for potential mediators (HPSS, knowledge, SDSCA) of the intervention effect on A1C.²⁴ These potential mediators are intermediate outcomes of the intervention that are hypothesized to serve as mechanisms or pathways through which the effect of the intervention on the ultimate outcome is achieved. We conduct the analyses by entering the HPSS, knowledge, and SDSCA variables into the regression model containing the treatment variable in a preselected order according to the conceptual model which the intervention is based upon, and observing the patterns of attenuation in treatment effects.

All analyses were conducted using STATA (version 9.0, College Station, TX) and SAS (version 9.1, Cary, NC).

RESULTS

Participant Characteristics

Participant accrual, enrollment, and retention are shown in the CONSORT flow diagram (Fig. 1). To reach recruitment goals, 139 persons were screened for eligibility and completed baseline visits. Eighty-two (58.9%) met eligibility criteria, and 56 (68.3 %) eligible persons enrolled and were randomized. Fifty-three of 56 participants completed the 3-month post-intervention follow-up visit, for a retention rate of 94.6%.

Selected baseline characteristics are presented in Table 1. The sample was 59% female, with a mean age of 61 years. Mean diabetes duration was 14 years, and several reported history of heart disease (33%), stroke (19%), or diabetes-related amputation (8%). The vast majority of participants were in poverty, and 30% of the sample had very low literacy (<5th grade reading level). Compared with those who participated in the intervention trial, eligible persons who refused participation were slightly younger (56.1 ± 10.7), and a larger percentage were female (89%). However, participants and refusers did not differ in income, education, literacy, or A1C.

Intervention Participation Rates

In the intensive group, 12 (41.5%) participants attended all 9 intervention sessions; a total of 25 (86.4%) attended 7 or more sessions. All participants attended at least half of the sessions. In the condensed group, 26 (93.6%) attended both sessions; one participant attended 1 of 2 sessions.

Effect on Clinical and Behavioral Outcomes

Figure 2 displays changes in the primary outcome, A1C, at 3 months post-intervention. The between-group treatment effect was -0.72% ($p=0.02$). At the group level of analysis, the interventions did not result in significantly improved blood

Figure 1. CONSORT Flow diagram of participant accrual, enrollment, and retention. Participants were low income, African-American patients with type 2 diabetes recruited from a diabetes registry of a university-affiliated managed care organization.

pressure or lipids. However, at the 3-month post-intervention follow-up, among the subgroup of intensive intervention participants who had suboptimal LDL at baseline, 6 (75%) showed individual improvement in LDL, with a median reduction of -25.0 mg/dl. Among those with suboptimal baseline DBP, 8 (67%) had individual improvements in DBP, with a median reduction of -7.17 mmHg. And, of those with suboptimal baseline SBP, 9 (47%) showed individual improvements in SBP, with a median reduction of -14.67 mmHg.

Table 2 shows changes from baseline in knowledge, problem solving, barriers, and self-care behavior scores. At immediate post-intervention, participants in both programs demonstrated knowledge gain. However, at 3 months post-intervention, knowledge was not maintained in the condensed intervention, while the intensive intervention was effective in improving knowledge, problem-solving skills, and self-management behavior scores. Of the SDSCA subscales, increased days adhering to general diet recommendations (1.20 ± 2.45 , $p=0.02$), accounted for improved self-care scores in the intensive group. Effect sizes for knowledge and problem-solving were both above the 0.5 criterion for clinically meaningful change in behavioral variables.²⁵ Change in HPSS, by baseline tertile of HPSS for the combined groups, indicated a pattern of greater improvement in problem solving by those with the lowest baseline scores (mean HPSS change: 1.41, 0.50, and 0.42, respectively), although non-statistically significant. Difficulty ratings for the most frequently-reported barriers at baseline decreased significantly at 1-week post-intervention. Exami-

nation of 3-month post-intervention ratings revealed initial participants no longer reporting those baseline barriers, while other participants newly reported one or more of those barriers, but with lower difficulty ratings than were reported at baseline.

Potential Mediators of Intervention Effect on A1C

In univariate analyses (Table 3), HPSS at 3 months post-intervention was significantly associated with change in A1C, while knowledge and total SDSCA at 3-month follow up were not. In multivariate analyses, adjusting for HPSS at follow up attenuated the intervention effect on change in A1C from -0.72% to -0.57% , while addition of other potential mediators did not alter the results substantially.

Patient Ratings of Usability and Satisfaction

Participants in both interventions rated their patient workbooks equally high in helpfulness, ease of understanding, and ease of visual presentation (all means >4.71 on a scale from 1–5). Similarly, the group sessions were rated equally high in helpfulness, ease of understanding the verbally presented material, and overall satisfaction with the self-management education program (all means >4.75). Consis-

Table 1. Selected Sample Characteristics at Baseline^a

Characteristic	Total Sample (N=56)	Intensive Intervention (n=29)	Condensed Intervention (n=27)
Sociodemographic			
Age (years)	61.3±10.9	61.1±11.0	61.5±10.9
Female Gender	33 (58.9)	15 (51.7)	18 (66.7)
Education (years)	11.4±3.0	11.1±3.2	11.8±2.8
Annual Household Income <\$9,600	20 (36.4)	11 (37.9)	9 (34.6)
Living in Poverty ^b	32 (57.1)	20 (69.0)	12 (44.4)
Insurance Status			
Medicare	17 (30.4)	9 (31.0)	8 (29.6)
Medicaid	14 (25.0)	9 (31.0)	5 (18.5)
Other Capitated Plan	16 (28.6)	5 (17.2)	11 (40.7)
Other Fee-for-Service Plan	9 (16.1)	6 (20.7)	3 (11.1)
Marital Status			
Married	11 (19.6)	7 (24.1)	4 (14.8)
Widowed/Separated/Divorced	29 (51.8)	12 (41.3)	17 (62.9)
Never Married	16 (28.6)	10 (34.5)	6 (22.2)
Literacy^c			
Post High School	10 (21.3)	6 (22.2)	4 (20.0)
9th—12th Grade	13 (27.7)	5 (18.5)	8 (40.0)
5th—8th Grade	15 (26.8)	10 (34.5)	5 (18.5)
≤ 4th Grade	17 (30.3)	8 (27.9)	9 (33.3)
Health-Related			
Diabetes Duration	14.4±8.6	13.8±8.9	15.0±8.3
Prior Diabetes Education (Yes responders)	41 (73.2)	20 (69.0)	21 (77.8)
Prior Dietician Visit (Yes responders)	41 (73.2)	20 (69.0)	21 (77.8)
Diabetes Medication			
None	6 (10.7)	3 (10.3)	3 (11.1)
Prescribed Pills Only	30 (53.5)	15 (51.7)	15 (55.5)
Prescribed Insulin Only	10 (17.9)	4 (13.8)	6 (22.2)
Prescribed Pills and Insulin	10 (17.9)	7 (21.4)	3 (11.1)
Prescribed Blood Pressure Medication	27 (79.4)	14 (82.4)	13 (76.5)
Prescribed Cholesterol Medication	19 (55.9)	11 (64.7)	8 (47.1)
Suboptimal Disease Control			
A1C ≥ 7.0%	48 (85.7)	24 (82.8)	24 (88.9)
Systolic Blood Pressure ≥ 130 mmHg	36 (64.3)	20 (67.0)	16 (59.3)
Diastolic Blood Pressure ≥ 80 mmHg	20 (35.7)	13 (44.8)	7 (25.9)
LDL Cholesterol ≥ 100 mg/dl	23 (41.1)	8 (27.6)	15 (55.6)
HDL Cholesterol ≤ 50 mg/dl (women)	0	0	0
HDL Cholesterol ≤ 40 mg/dl (men)	5 (8.9)	3 (10.3)	2 (7.4)
BDI-Medical Patients	1.49±2.3	1.66±2.3	1.31±2.24

BDI-Medical Patients: Beck Depression Inventory Fast Screen for Medical Patients. Scores range 0–21

Data are N (%) or means±SD

^aRandomization groups did not differ on any baseline characteristics (all $p > 0.05$)

^bParticipants in poverty based on 2005 Federal Register guidelines of income and number of persons per household

^cWRAT-3 Reading Grade Level, based on standardized scores

tent with the observed effect, the intensive program was rated higher than the condensed in amount learned (4.88 ± 0.33 vs. 4.46 ± 0.72 , $p = 0.01$) and amount of new information presented (4.65 ± 0.63 vs. 4.08 ± 0.93 , $p = 0.01$).

Figure 2. Effect of the low-literacy adapted, DECIDE problem-based diabetes self-management training in an intensive and a condensed delivery format. Change scores are coefficient estimates of the mixed-effects model, parameterized by visit indicators (baseline and 3-month follow-up), intervention group indicator (intensive and condensed), and interaction terms between the visit and group indicators. The between-group difference in A1C change scores = -0.72 , $p = 0.02$.

DISCUSSION

Developing a problem-based self-management training in both an intensive and condensed format, adapted for low literacy, was feasible. Both the intensive format, which modeled standard PST, and the condensed format, which more closely modeled current practice in diabetes, covered the necessary components of PST as a behavior change intervention. Participants in each intervention experienced the program as helpful and easy to understand. At immediate post-intervention, participants in both programs demonstrated knowledge gain. However, at 3 months post-intervention, only the intensive intervention was effective in improving knowledge, problem-solving skills, self-care, and A1C. This study extends findings regarding effective elements of PST delivery²⁶ to diabetes and suggests that a traditional PST delivery model (intensive), but not an abbreviated model is effective for key diabetes behavioral and clinical outcomes.

Our treatment effect on A1C of -0.72% at 3 months post-intervention is higher than mean reductions reported in meta-analyses of diabetes self-management educational and behavioral interventions of 0.43% overall,²⁷ and 0.26% at 1–3 months of follow-up.²⁸ Problem-solving skill at follow-up seems to partially mediate the treatment effect on A1C, as it attenuated the observed treatment effect on A1C change by 0.15% . Although this attenuation only reach marginal statistical significance in this small pilot trial, it may warrant further investigation in future studies. Few changes were observed from baseline to follow-up in frequencies of participants prescribed diabetes medications (none, pills only, insulin only, insulin and pills), further suggesting that changes in A1C were generally not due to medication initiation or advancement. In fact, one participant in the intensive program who was on insulin and oral agents at baseline was able to successfully discontinue insulin during follow-up.

Neither intervention had a significant effect on blood pressure or lipids at the group level of analysis. One explanation is that, unlike A1C, smaller subsets of participants had suboptimal blood pressure at baseline, and fewer had suboptimal lipids

Table 2. 1-Week and 3-Month Post-Intervention Changes in Behavioral Outcomes

Characteristic	Condensed Intervention					Intensive Intervention				
	Baseline ^a	1-Week ^b	P value	3- Month ^b	P value	Baseline ^a	1-Week ^b	P Value	3-Month ^b	P value
Knowledge	5.3±1.6 (2.0, 7.0)	1.6 [0.8, 2.3] (d=0.83)	<0.01	0.6 [-0.1, 1.4] (d=0.37)	0.10	4.1±1.3 (2.0, 8.0)	1.2 [0.5, 1.9] (d=0.64)	<0.01	1.3 [0.6, 2.0] (d=0.63)	<0.01
HPSS	21.3±2.5 (15.6, 28.0)	0.3 [-0.7, 1.3] (d=0.10)	0.52	0.5 [-0.2, 1.3] (d=0.27)	0.18	22.0±2.3 (15.0, 25.0)	0.6 [-0.5, 1.6] (d=0.18)	0.30	1.1 [0.3, 1.9] (d=0.55)	0.01
Barrier Difficulty Rating ^c	6.0±2.5 (1.0, 10.0) (d= -0.16)	-0.5 [-1.9, 0.8]	0.44	-0.5 [-1.8, 0.8] (d= -0.17)	0.48	6.4±1.9 (2.3, 10.0)	-1.4 [-2.6, -0.2] (d= -0.42)	0.02	-0.9 [-2.1, 0.3] (d = -0.32)	0.14
SDSCA ^d	65.4±15.3 (28.0, 92.0)	—	—	2.9 [-1.0, 6.8] (d=0.32)	0.15	61.0±14.0 (39.0, 87.0)	—	—	4.0 [0.1, 7.8] (d=0.33)	0.04

HPSS: Health Problem-Solving Scale. SDSCA: Summary of Diabetes Self-Care Activities scale

^aBaseline data are means±SD and (ranges)

^b1-Week and 3-Month Post-Intervention data are coefficient estimates of the mixed-effects model (95% Confidence Intervals), parameterized by visit indicators (baseline and 3-month follow-up), intervention group indicator (intensive and condensed), and interaction terms between the visit and group indicators. Effect Size, Cohen's d (d), is computed by dividing the mean difference between baseline and follow-up scores by the SD for each group [$X_2 - X_1$ /pooled SD]

^cBarriers Difficulty Rating reflects total mean ratings for the 5 most frequently reported self-management problems in each group at baseline, and total mean ratings in those same 5 self-management problems at each of the subsequent follow-up time points. For the intensive Intervention group, the 5 most frequently reported self-management problems were: managing diet, getting physical activity, self-monitoring, managing weight, and managing diabetes complications and symptoms. For the condensed Intervention group, the 5 most frequently reported were: managing diet, getting physical activity, managing medications, managing weight, and managing diabetes complications and symptoms

^dSDSCA was assessed at baseline and at 3 months post-intervention only

(Table 1). Intervention effects seen in these subgroups yielded smaller mean change in these outcomes when averaged over the entire group. Importantly, the individual changes patients experienced in SBP, DBP, and LDL were clinically meaningful.

Table 3. Predictors of Change in A1C in Intensive Intervention Group

	Change in A1C ^a	Change in A1C Model 1 ^b	Change in A1C Model 2 ^c
Treatment	-0.72 (-1.42, -0.01) p=0.046	-0.57 (-1.28, 0.13) p=0.110	-0.53 (-1.28, 0.22) p=0.159
HPSS at 3 months post-intervention	-0.13 (-0.26, -0.01) p=0.037	-0.11 (-0.23, 0.02) p=0.089	-0.06 (-0.20, 0.07) p=0.354
Knowledge at 3 months post-intervention	0.06 (-0.13, 0.26) p=0.523	—	0.03 (-0.17, 0.23) p=0.752
SDSCA at 3 months post-intervention	-0.02 (-0.04, 0.01) p=0.175	—	-0.01 (-0.04, 0.02) p=0.419
HPSS change	-0.11 (-0.29, 0.07) p=0.217	—	—
Knowledge change	0.06 (-0.15, 0.27) p=0.559	—	—
SDSCA change	-0.001 (-0.04, 0.04) p=0.956	—	—

HPSS: Health Problem-Solving Scale. SDSCA: Summary of Diabetes Self-Care Activities scale

Data are unstandardized regression coefficients (95% CI)

^aUnivariate model

^bTreatment+HPSS at follow up

^cTreatment+HPSS at follow up+Knowledge at 3 months post-intervention +SDSCA at 3 months post-intervention

This was a comparative effectiveness study of two active interventions rather than an examination of an active intervention vs. a control condition. An attention control is not appropriate in this study design,²⁹ as it would not allow comparison of the actual behavioral procedures as they are implemented in practice. The condensed format can be considered a “best practices” version of the current, brief approaches to problem-solving training within diabetes patient education, which tend to be less structured and less comprehensive in use of the formal PST approach.^{9,11}

One of the strengths of our study was the high trial completion rate, resulting in few missing data. In such a case, some may consider using the “complete case” analysis, wherein only the outcome differences between baseline and follow-up among patients who completed the trial are used for the analysis. The results of such analyses would only be valid if data were missing completely at random. Instead, we opted to use the mixed effects modeling approach for our ITT analysis, an approach that is valid, with proper modeling, under the more realistic case where the probability of missing data may depend on the variables observed in the study.

The study has limitations. Due to the sample size, we were not powered to detect between-group changes in outcomes other than A1C. The effect sizes for knowledge, HPSS, and SDSCA yielded by this study will aid sample size planning for future evaluations of those behavioral variables. Second, this study was focused on intervention development and testing of feasibility and acceptability. As such, the follow-up period was of relatively short duration (3 months post-intervention, corresponding with 6–9 months following baseline assessment). Nevertheless, the study demonstrated statistically significant between-group changes in A1C as well as significant within-group improvements in a number of key behavioral parameters, showing promise for effectiveness. The intensive program requires testing with a longer follow-up period to

monitor maintenance of the observed skill gain, which has been found to improve with time when problem-solving has been taught effectively,¹¹ maintenance of clinical improvements, and cost-effectiveness of this intervention approach.

Finally, the study addresses a delivery model consideration. There has been a shift toward more social- and community-based interventions for improving diabetes control in vulnerable populations, as those approaches have many advantages. Moreover, reviews of the evidence base have concluded that vulnerable populations may not benefit as much from clinic-based, didactic, moderate intensity approaches.³⁰ In contrast, our study suggests that clinic-based interventions can succeed in these populations. Adoption and attendance were high with delivery within a healthcare setting. Second, providing rather rigorous content and didactic materials was acceptable and deemed useful. Participants reported taking their workbooks with them to the grocery store, doctors' appointments, and sharing with coworkers and family. Importantly, this clinic-based delivery required that materials be designed for suitability, which is feasible and effective using available guidelines. Finally, while more social-based interventions may be particularly useful for support-building, the combined education and problem-solving training intervention is designed for skill-building for behavior change;¹¹ participants found the approach relevant due to its focus on life challenges that stood in the way of managing their diabetes. With newer healthcare approaches to chronic disease care, such as patient-centered medical home, ways of providing effective self-management training, particularly for vulnerable populations, are needed. Combining education with problem-solving training for behavior change is a viable, reimbursable treatment within some existing practice models,³¹ and it may be an approach for delivery by healthcare professionals within the newer self-management support models.

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