Are Benefits From Diabetes Self-Management Education Sustained?

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Objectives: To evaluate whether outcomes from diabetes self-management education for patients with suboptimal control were sustained.

Study Design: A randomized controlled trial of 623 adults with type 2 diabetes and glycated hemoglobin (A1C) ≥7% assigned to receive conventional individual education (IE), group education (GE) using US Diabetes Conversation Maps, or usual care (UC) with no education.

Methods: A1C tests, Problem Areas in Diabetes (PAID), Diabetes Self-Efficacy (DES), Recommended Food Score (RFS), physical activity, and medication use were quantified at baseline and 1 year of follow-up through electronic health records and quarterly mailed surveys. Short-term (mean 6.8 months) and long-term (12.8 months) outcomes were evaluated using linear mixed models. In addition, follow-up trajectories were plotted in a random effects generalized additive model with smooth splines.

Results: Compared with UC, IE resulted in long-term improved DES and PAID scores (DES, \pm .11, P=.03 and PAID, \pm .294, \pm .04), but not significantly improved long-term RFS or physical activity change. The A1C trajectory declined more steeply in IE than GE and UC for the first 150 days post randomization. However, by 250 days, there was no treatment group A1C difference. The model fit likelihood ratio test for A1C intervention trends was significant for 3 distinct non-linear trajectories (\pm 02).

Conclusions: Conventional IE (but not GE) resulted in significant and sustained improvements in self-efficacy and reduced diabetes distress compared with UC, but short-term improvements in A1C, nutrition, and physical activity were not sustained. Patients may need ongoing reinforcement to achieve lasting behavioral change and glucose control.

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For author information and disclosures, see end of text.

any patients with diabetes have not achieved their optimal care goals and have difficulty following recommendations for self-management. A better understanding of how to help these patients improve and sustain self-management behaviors is important to overcoming the public health and cost concerns related to the increasing prevalence of diabetes in our population.²

Studies of outcomes related to diabetes self-management education (DSME) have shown mixed results, and a 2007 meta-analysis rated most studies on the topic as poor to moderate in quality.³ More recently published research has been judged of higher quality due to masking of outcome assessments, fewer numbers of subjects lost to follow-up, and analysis by intent-to-treat.⁴ These studies suggest that educational interventions that more strongly incorporate individual goal-setting and tailored behavioral change strategies, whether delivered in an individual or group setting, most successfully help patients improve blood sugar control in the short term (up to 6 months of follow-up).^{5,6} However, a large meta-analysis of the effect of self-management education on longer-term glycemic control showed that the glycated hemoglobin (A1C) effect from DSME was not sustained after 4 months.⁷ More research is needed to evaluate the effect of educational strategies on more long-term outcomes and on medication use.^{5,6}

The Journey for Control of Diabetes Interactive Dialogue to Educate and Activate (IDEA) study was a randomized controlled trial that compared methods of individual education (IE) and group education (GE) with usual care (UC) in patients with relatively long-standing diabetes (mean duration, 11 years) and suboptimal control (mean A1C, 8.3%). Previously published short-term results (ie, about 6 months) demonstrated that subjects randomized to IE, but not GE, had improvement in psychosocial outcomes as well as glucose control and behavioral outcomes.⁵ In this analysis, we hypothesized these IE improvements would be sustained after a year of follow-up compared with the UC group, and that there would be no significant change in outcomes for the GE subjects after a year of follow-up.

METHODS

The study was reviewed in advance, approved, and monitored on an ongoing basis by the HealthPart-

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ners (HP) Institutional Review Board and Ethical and Independent Review Services, and registered at clinicaltrials. gov NCT00652509.

Study Population

Between 2008 and 2009, the study enrolled 623 patients from ABQ Health Partners in Albuquerque, New Mexico, and HP Clinics in Minneapolis, Minnesota, who met the eligibil-

ity criteria of type 2 diabetes and an A1C result of ≥7% in the last 6 months.⁸ Potentially eligible subjects were mailed a letter of invitation to participate and offered gift cards worth \$50 for completing the baseline and enrollment visit and \$25 for each of 4 mailed follow-up surveys. Consented subjects were randomly assigned to GE, IE, or UC using a random allocation sequence in a 2:2:1 ratio. Patients were scheduled for all of their IE and GE sessions at the enrollment visit but could call to reschedule at any time during the intervention period. See Figure 1 for the IDEA Study design and CONSORT (Consolidated Standards of Reporting Trials) patient flow. A1C outcomes of the non-enrolled (NE) population, consisting of 7977 patients who received letters of invitation to participate in the study but did not enroll, were also tracked.

Interventions

The IE intervention consisted of three 1-hour individual sessions spaced approximately 1 month apart and were delivered by either nurse or dietitian certified diabetes educators using the conventional method of the care system (the accredited education method used for members not enrolled in the study and reimbursable by Medicare). The first session included an assessment of patient needs pertaining to American Association of Diabetes Educators (AADE)-recommended content⁹ for 7 self-care behaviors (healthy eating, monitoring blood sugars, taking medications, problem solving, risk reduction, healthy coping, and being active). Follow-up sessions focused on the patient's individual concerns, reviewed selfmonitored blood sugars, and evaluated progress toward treatment targets. The sessions were intended to help the patient develop personalized behavioral modification goals needed to achieve care targets.

The GE intervention consisted of four 2-hour sessions scheduled 1 week apart delivered by the same certified diabetes educators (nurses and dietitians) using the US Diabetes Conversation Map program endorsed by the American Diabetes Association (ADA). The program was a non-didactic group approach that promoted patient interaction and was in-

Take-Away Points

The study adds to the current literature on diabetes self-management education (DSME) by evaluating and demonstrating sustained improvement of patient-centered outcomes (self-efficacy and distress) for patients with suboptimally controlled diabetes of long duration. It informs healthcare reform in the following ways:

- Improvements in such patient-centered outcomes support referral to diabetes educators and reimbursement of conventional DSME for patients with suboptimal control of diabetes (glycated hemoglobin >7%).
- Ongoing reinforcement may be needed to more fully realize the impact of diabetes education and to yield sustainable improvements in nutrition, exercise, and blood sugar control.

tended to help patients overcome barriers to self-management and to improve self-efficacy. ¹¹ Conversation Map programs are currently being used in an estimated 105 countries in 34 different languages. ¹⁰ The content also meets the requirements for ADA diabetes education program accreditation, but currently a comprehensive program of this length is reimbursable by Medicare only in the first year of diagnosis and so was considered non-conventional for patients such as IDEA with a longer duration of diabetes. The study educators received expert training on the Conversation Map program, and a fidelity check of the interventions included high mean scores on facilitator self ratings as well as high patient satisfaction scores after each session. ^{5,12}

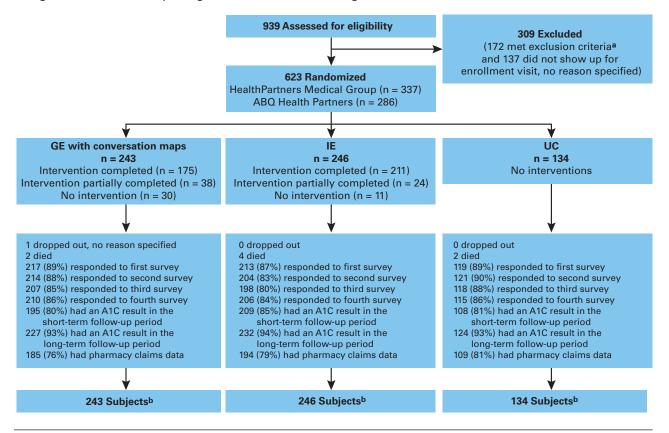
The UC group was not assigned any educational intervention throughout the study. The study did not prohibit self-management education recommended by usual providers or sought by the study subjects.

Data Collection

All study subjects received surveys at the baseline visit and by mail at 1, 4, 7, and 10 months after the last scheduled educational intervention. For the UC group, a proxy date for the last scheduled intervention was calculated using the mean value of IE and GE intervention subjects. Survey outcome variables for this analysis were obtained from validated instruments that were previously defined and demonstrated to be responsive in the short-term results.⁵ These variables are described in **Table 1**.¹³⁻¹⁸

A1C values and measurement dates for all study subjects and the NE population were collected through passive surveillance of laboratory results contained in the electronic health record (EHR). A1C tests were analyzed at one of 2 accredited clinical laboratories using standard high-pressure liquid chromatography assay methods with a coefficient of variation (CV) of 1.14% at an A1C of 7.5% (HP Clinics) and a CV of 0.82% at an A1C of 6.2% (ABQ Health Partners). All A1C data were collected and retained for subjects for 6 months before the baseline randomization date and for 12.8 months post-randomization. The periods between the last

■ Figure 1. The IDEA Study Design and CONSORT Flow Diagram



A1C indicates glycated hemoglobin; CONSORT, Consolidated Standards of Reporting Trials; GE, group education; IDEA, Interactive Dialogue to Educate and Activate; IE, individual education; UC, usual care.

^aDeclined participation after learning more about the study; had visual, hearing, or cognitive impairment; was 85 years or older; or was unable to read English.

^bAll subjects were included in the intent-to-treat analysis. Latest results were carried forward if a result was missing in the follow-up period.

scheduled educational session and the second survey mailing date (4 months after the last scheduled educational session) and fourth survey mailing date (10 months after the last scheduled educational session) were used to determine the short- and long-term follow-up intervals for A1C, equating to a mean of 6.8 months and 12.8 months of follow-up from the baseline visit.⁵ For the non-enrolled study population, a "baseline date" was imputed from the screening and baseline visit time patterns observed for consented subjects.

Medication data were obtained through surveillance of medical claims on the subset of subjects (n = 488, 78%) with health plan pharmacy coverage through the research-delivery organizations. Medication use was determined for 5 classes of glycemic medications (insulins, biguanides, sulfonylureas, dipeptidyl peptidase-4 [DPP4] inhibitors, and glucagon-like peptide [GLP1] agonists) at three 6-month measurement periods: 6 months prior to enrollment (baseline), the first 6 months after enrollment (short-term follow-up), and 6 to 12 months after enrollment (long-term follow-up). Medication use was defined as having any claim for a drug in that class in the measurement

period. The number of drug classes used by the patient was tallied for each patient by measurement period. Medication intensification was defined in the short-term and long-term follow-up periods as an increase in the total number of drug classes, or newly identified insulin use, compared with the baseline period.

Additionally, the study tracked the number of diabetes education visits as a secondary outcome through claims data using patient visit codes for educational services. The variable was the sum of the number of visits obtained outside of the assigned study sessions from the baseline date to the end of the short-term and long-term follow-up measurement periods.

The purpose of this analysis was to evaluate the effects of diabetes education of IDEA study subjects on glycemic control, psychosocial and behavioral outcomes, and medication use over a follow-up period of approximately 1 year. All statistical analyses were conducted with SAS version 9.2 software (Cary, North Carolina) and R 2.13.0.19 Study outcome trajectories were analyzed using a general linear mixed model for all

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■ Table 1. Survey Measurement Descriptions

Survey Domain	Survey Instrument and Description			
Race/Ethnicity	Categorical variable from multiple choice response			
Education	Categorical variable from multiple choice response			
Income	Categorical variable from multiple choice response			
Marital status	Categorical variable from multiple choice response			
Duration of diabetes	Mean number of years as calculated from the response to "Year you were first told you have diabetes"			
Depression	Measured by the PHQ-9 depression module ¹³			
Understanding	DCP section to assess understanding. The component score is the mean of a set of questions scaled 1-5, with 5 being more favorable 14			
Diabetes distress	PAID: A 20 item measure ^a of diabetes-specific emotional distress scaled 0-100 with higher scores indicating greater distress ¹⁵			
Diabetes empowerment	DES-SF: The average score of 8 items measuring self-efficacy in people with diabetes (values ranging from 1-5 with 5 indicating higher levels of empowerment) ¹⁶			
Nutrition	RFS: A summary score ranging from 0-23 of 23 items recommended by current dietary guidelines consumed at least once per week ¹⁷			
Physical activity	BRFSS method: Physical activity score (minutes per week of moderate-level activity) ¹⁸			

BRFSS indicates behavioral risk factor surveillance system; DCP, diabetes care profile; DES-SF, diabetes empowerment scale—short form; PAID, problem areas in diabetes; PHQ-9, 9-item Patient Health Questionnaire; RFS, recommended food score.

normally distributed continuous variables (A1C, PAID, DES, RFS). A1C was log-transformed in the analysis and then retransformed back to its original scale (presented as geometric means). A generalized linear model with binomial distribution applying the generalized estimating equation (GEE) method was used to analyze the proportion of subjects meeting A1C control criteria, participating in moderate physical activity, and receiving medication intensification. Mean counts of medication classes and number of education encounters outside the intervention correspond to geometric means estimated with a generalized linear model with Poisson distribution. Pair-wise comparisons between intervention groups correspond to the ratio of the estimated geometric means.

Covariates included in the models were baseline A1C, age, study site, and duration of diabetes. Additional covariates were included specific to each model. Intervention effects for survey outcomes were tested using the second and fourth follow-up survey results. Intervention effects for A1C were tested using the A1C with the latest date collected in previously defined short-term and long-term follow-up intervals after randomization. Missing values for A1C and survey outcomes in the measurement period of interest were assigned the latest known result (eg, the baseline value if no subsequent data were collected). Pair-wise comparisons of changes from baseline for GE and IE were conducted in relation to UC.

An additional analytic approach evaluated cross-sectional comparisons plotted with 95% confidence interval (CI) at baseline, and follow-up surveys (1, 4, 7, and 10 months after

the last scheduled educational intervention). A generalized additive linear mixed model was used to produce a smooth function of A1C trajectory according to intervention group, using all A1C repeated measures occurring from 30 days before randomization date to 385 days after. The pre-intervention trend line before 30 days was eliminated due to increasingly scarce data points that could overly influence the A1C trajectory and limit valid interpretation. Differences in trajectories between intervention treatment groups were assessed using a likelihood ratio test (LR-T).

RESULTS

Of 623 total subjects, 337 (54%) were associated with HP Clinics, and 286 (46%) were associated with ABQ Health Partners. Randomization resulted in balanced group characteristics for enrolled subjects, with a mean age of 62, 49% women, 22% high school education or less, 64% married, 65% white, 5% black, and 22% Hispanic. Mean duration of diabetes was 11.7 years.⁵

Table 2 shows that, in the short-term follow-up period, IE resulted in a .25% absolute reduction in A1C (P = .03) and an odds ratio of 1.83 (1.05-3.17) for achieving an A1C <7% compared with UC, but the A1C effect was not sustained in the long-term follow-up interval (-.09%, P = .50) and odds ratio .91 (0.56-1.49). No significant intervention effects were noted for GE compared with UC in the short term or long term. Rate of medication intensification in the

^aOne PAID question was inadvertently omitted on the survey resulting in a PAID score based on 19 instead of 20 questions

■ Table 2. Changes in Glycemic Control, Survey Outcomes, Medication Use and Intensification, and Outside Education Rates in the Short-term and Long-term Follow-up Periods

	Group Values			Pair-Wise Comparisons to UC	
				IE-UC	GE-UC
	UC	IE	GE	Mean	Mean
Outcome	(n = 134)	(n = 246)	(n = 243)	difference (P)	Difference (P)
Glycemic control (mean A1C), %					
Mean A1C at baseline	8.09	8.11	8.07		
Short-term follow-up change (<i>P</i>)	-0.27 (.004)	-0.51 (<.001)	-0.26 (<.001)	-0.25 (.03)	0.01 (.97)
Long-term follow-up change (<i>P</i>)	-0.42 (<.001)	-0.35 (<.001)	-0.31 (<.001)	-0.09 (.50)	0.11 (.33)
Understanding (from DCP)					
Mean score at baseline	3.01	3.02	3.01		
Short-term follow-up change (<i>P</i>)	0.28 (<.001)	0.52 (<.001)	0.49 (<.001)	0.24 (<.001)	0.21 (.002)
Long-term follow-up change (<i>P</i>)	0.34 (<.001)	0.59 (<.001)	0.53 (<.001)	0.25 (<.001)	0.19 (.003)
Empowerment (from DES-SF)					
Mean score at baseline	3.78	3.8	3.79		
Short-term follow-up change (<i>P</i>)	0.05 (.24)	0.15 (<.001)	0.05 (.10)	0.10 (.06)	0.00 (.97)
Long-term follow-up change (<i>P</i>)	0.00 (.98)	0.11 (<.001)	0.06 (.06)	0.11 (.03)	0.06 (.26)
Distress (from PAID)					
Mean score at baseline	30.52	29.81	29.62		
Short-term follow-up change (<i>P</i>)	-4.51 (<.001)	-6.77 (<.001)	-4.22 (<.001)	-2.26 (.11)	0.29 (.84)
Long-term follow-up change (<i>P</i>)	-4.83 (<.001)	-7.77 (<.001)	-5.04 (<.001)	-2.94 (.04)	-0.21 (.88)
Nutrition (from RFS)					
Mean score at baseline	12.34	12.34	12.36		
Short-term follow-up change (P value)	0.02 (.95)	0.57 (.001)	0.44 (.01)	0.55 (.06)	0.42 (.16)
_ong-term follow-up change (<i>P</i> value)	0.47 (.05)	0.66 (<.001)	0.60 (<.001)	0.19 (.53)	0.13 (.67)
Moderate physical activity, minutes/week	(from BRFSS)				
Mean score at baseline	134	125.56	121.63		
Short-term follow-up (change <i>P</i>)	-19.91 (.17)	15.23 (.15)	8.14 (.45)	65.14 (.05)	28.05 (.12)
Long-term follow-up change (<i>P</i>)	-7.09 (.63)	3.65 (.73)	17.02 (.11)	10.74 (.55)	24.11 (.18)
Participation in moderate physical activity	/ (rate) (%) and (OR of achieving n	noderate levels	OR (95% CI)	OR (95% CI)
At baseline	74	77	75		
Short-term follow-up rate	78	80	74	1.12 (.66-1.91)	0.79 (.47-1.32)
Long-term follow-up rate	74	74	72	0.98 (.61-1.58)	0.89 (.55-1.42)
Total count of glycemia drug classes ^a ; me	Ratio of means (95% CI)	Ratio of means (95% CI)			
Baseline	1.68 (1.45-1.94)	1.73 (1.55-1.92)	1.69 (1.51-1.88)		
Short-term follow-up mean count (95% CI)	1.68 (1.46-1.94)	1.70 (1.52-1.89)	1.78 (1.59-1.98)	1.00 (.84-1.21)	1.06 (.88-1.27)
Long-term follow-up mean count (95% CI)	1.57 (1.36-1.83)	1.61 (1.44-1.80)	1.71 (1.53-1.91)	1.02 (.85-1.23)	1.09 (.90-1.31)
Rate of insulin treatment ^b (%) and OR of i	nsulin use			OR (95% CI)	OR (95% CI)
Baseline	36.7	32.5	22.7		
Short-term follow-up rate	34.2	30.6	30	0.85 (.49-1.48)	0.78 (.45-1.38)
Long-term follow-up rate	30.9	30.6	30.9	0.99 (.56-1.72)	1.00 (.57-1.78)
Rate of medication intensification ^c (%) an	d OR of having r	medication intens	sified	OR (95% CI)	OR (95% CI)
Short-term follow-up rate	17.6	15	20.6	0.83 (.44-1.57)	1.22 (.66-2.26)
Long-term follow-up rate	19.4	16	18.1	0.79 (.43-1.47)	0.92 (.50-1.68)
Rate of patients with A1C <7% (%) and OI	OR (95% CI)	OR (95% CI)			
Short-term follow-up rate	12.6	20.9	13.5	1.83 (1.05-3.17)	1.08 (.62-1.90)
Long-term follow-up rate	27	25.3	20.7	0.91 (.56-1.49)	0.70 (.43-1.15)
Number of outside educational visits and	Ratio of means (95% CI)	Ratio of means (95% CI)			
Short-term follow-up (mean number)	0.21	0.75	0.44	3.64 (2.44-5.40), <.001	2.12 (1.40-3.21), <.0
Long-term follow-up (mean number)	0.42	0.84	0.63	2.02 (1.51-2.71), <.001	1.51 (1.11-2.05), .00

A1C indicates glycated hemoglobin; BRFSS, behavioral risk factor surveillance system; CI, confidence interval; DCP, diabetes care profile; DES-SF, diabetes empowerment scale-short form; GE, group education; IE, individual education; OR, odds ratio; PAID, problem areas in diabetes; RFS, recommended food score; RR, relative risk; UC, usual care.

Rates of treatment intensification were adjusted for gender, duration of diabetes, medication counts of glycemia medications and insulin use at baseline, A1C at baseline, and study site. Counts of glycemia drug classes and rate of insulin treatment were adjusted for gender, diabetes duration, A1C at baseline, and

study site.

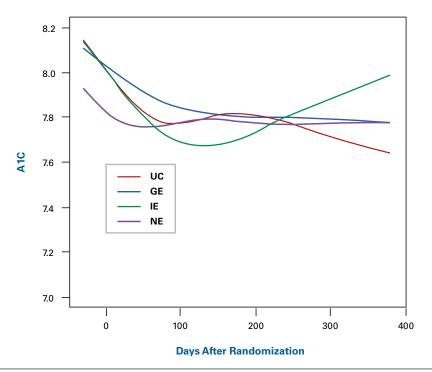
^aMean count of glycemia medication classes used by subjects determined by summing medications filled using pharmacy claims data.

^bThe percentage of patients who had an insulin pharmacy claim.

^cTreatment intensification was defined as an increase in the number of drug classes used or a new prescription of insulin during the observation period compared with baseline.

dThe mean number of educational visits outside of those scheduled through the research intervention, as determined by billing codes.

■ Figure 2. Continuous Trend of A1C Values by Intervention Group



A1C indicates glycated hemoglobin; GE, group education; IE, individual education; NE, non-enrolled; UC, usual care. Eligible study population using all available A1C values and dates from 30 days before baseline to 385 days after.

subgroup of patients with pharmacy claims (adjusted for differences in medication use in the baseline period) was lower in the short-term follow-up period for IE (15.0%) compared with UC (17.6%) and GE (20.6%) but did not reach statistical significance (overall test P = .35). Rates of medication intensification in the long-term follow-up period were similar (IE 16%, UC 19.4%, and GE 18.1%). For both IE and GE interventions versus UC, improvements in DCP understanding scores were observed in the short term (IE-UC, +.24, P <.001; GE-UC, +.21, P = .002) and long term (IE-UC +.25, P < .001; GE-UC +.19, P = .003). DES and PAID scores were also more favorable in the long term for IE than for UC (DES, +.11, P=.03; PAID -2.94, P=.04), but similar findings were not observed for GE versus UC. Trends in improvement for IE compared with UC for nutrition and physical activity observed in the short term were not observed long term. The mean number of educational services obtained by patients outside of the study interventions for IE was 2 times that of UC (ratio of means: 2.0 [1.5-2.7], P <.001) and for GE was 1.5 times (ratio of means: 1.5 [1.1-2.0], P = .009).

Figure 2 shows a continuous temporal trend of A1C values for each intervention group using all available A1C values within a date range from 30 days before baseline to 385 days after. The model fit test (LR-T) for intervention trends was

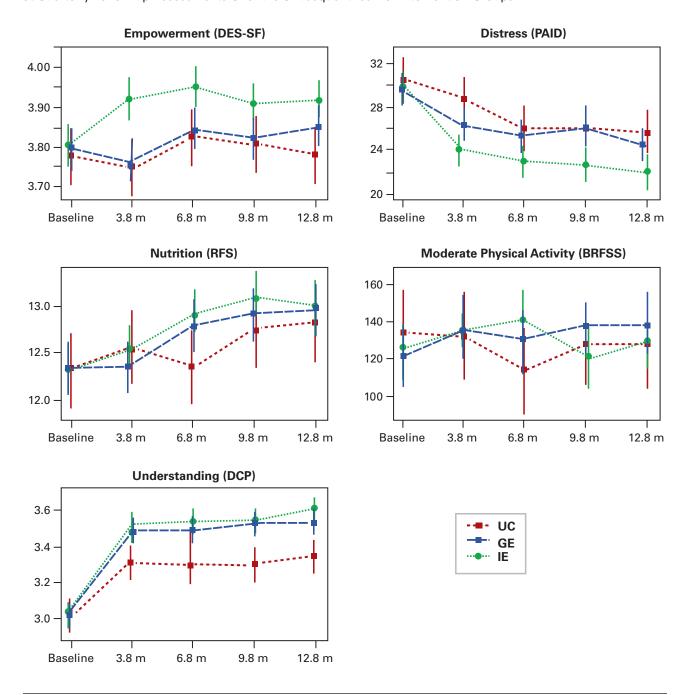
significant for 3 distinct non-linear trajectories (P = .02). The observed short-term improvement in A1C for IE relative to the other treatment group peaks at 120 days and was no longer present at 250 days. A similar A1C trajectory to UC was observed for the NE population.

Figure 3 shows the observed trends in psychosocial and behavioral outcomes from surveys conducted at baseline and at quarterly follow-up assessments over the subsequent year. Early and sustained improvements in DCP understanding scores were observed for IE and GE compared with UC. Trends for IE reveal statistically significant, sustained improvements in DES and PAID compared with UC over the long-term follow-up period, with similar but lesser trends for GE that were not statistically significant.

DISCUSSION

For patients with long duration of diabetes and suboptimal control, measures of patient understanding, self-efficacy, and diabetes distress improved in the short term from a brief intervention consisting of 3 hours of conventional individual diabetes education and were sustained over the long-term period. Despite the noted absence of sustained improvements in blood sugar control, the psychosocial measures (DES and

■ Figure 3. Observed Trends in Psychosocial and Behavioral Outcomes From Surveys Conducted at Baseline and at Quarterly Follow-up Assessments Over the Subsequent Year for Intervention Groups



BRFSS, behavioral risk factor surveillance system; DCP, diabetes care profile; DES-SF, diabetes empowerment scale–short form; GE, group education; IE, individual education; PAID, problem areas in diabetes; RFS, recommended food score; UC, usual care.

PAID) were psychometrically valid,²⁰ and outcomes were consistent with expert consensus of the desired key goals of DSME of improved knowledge and understanding, self-determination, self-management, and psychological adjustment.^{21,22} Improvements in such patient-centered outcomes

justify current DSME recommendations and reimbursement policy for IE for patients with diabetes of long duration and suboptimal control.²³

The group approach with Conversation Maps used in the study is popular among educators, with more than 35,000 edu-

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cators worldwide trained to use them¹⁰ and high educator satisfaction rates.¹² The non-conventional use of this approach in IDEA subjects, with long duration of diabetes and suboptimal control, did not result in improved patient outcomes in the short term or long term. However, the lack of improved outcomes observed in this study for GE subjects relative to IE is not necessarily related to the group nature of the education, and could be at least partially explained by hypothesizing that GE using Conversation Maps did not include some "essential ingredients" (eg, review of individual glucose logs and personalized behavioral goal setting and tracking) that could contribute to better patient outcomes.⁴ Other recent studies of group educational interventions have demonstrated improved A1C outcomes using a structured behavioral group approach that included individualized behavior change activities compared with an individual approach and a didactic group approach that included the importance of goal setting but no related structured activities. 6 The results highlight the need for additional research to more definitively identify the specific characteristics of educational interventions that mediate improved patient outcomes.

IE resulted in sustained higher measures of self-efficacy and lower diabetes distress than UC without sustained improvements in glucose control, nutrition, and physical activity. In addition there was a trend toward decreased likelihood of medication intensification in the IE group. The data suggest that the mechanism for early improved glycemic control compared with the other treatment groups was likely due to behavior change in conjunction with improved psychosocial outcomes, as opposed to medication intensification. However, improved self-management behaviors observed with IE in the short-term analysis were not sustained, which was possibly related to the brevity of the intervention and the little attention paid to the inevitable setbacks and relapses that occur with behavior change. Results were consistent with behavior change theory, showing that successful longterm strategies also need to support maintenance of health behaviors.24-27

This study is limited by several design features. The main outcome, A1C, was collected through passive surveillance of electronic records rather than dedicated study measurements. The methods of outcome collection resulted in missing data that could influence results. In this regard, it is reassuring that previous sensitivity analysis conducted on subgroups of patients without missing data and on completers of the intervention generated similar results. In addition, pragmatic research approaches (real-world interventions and outcomes) such as this could be advantageous when considering the generalizability to real clinical settings. Another limitation is that the medication analysis is considered exploratory because

it was limited to subjects with available pharmacy claims data and did not have sufficient power to draw significant conclusions.

Increasing patient self-efficacy and lasting behavior change is critical for our healthcare system to achieve goals of quality, safety, and cost-effectiveness in diabetes management. The conventional individual approach to DSME had significant value in improving understanding, confidence in managing the disease, and reducing related distress. However, these study results suggest that additional follow-up and supportive interventions directed at behavior change may be needed to more fully realize the full impact of diabetes education and to yield sustainable improvements in nutrition, exercise, and blood sugar control.

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