Dosage Effects of Diabetes Self-Management Education for Mexican Americans

The Starr County Border Health Initiative

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OBJECTIVE — The objective of this study was to compare two diabetes self-management interventions designed for Mexican Americans: "extended" (24 h of education, 28 h of support groups) and "compressed" (16 h of education, 6 h of support groups). Both interventions were culturally competent regarding language, diet, social emphasis, family participation, and incorporating cultural beliefs.

RESEARCH DESIGN AND METHODS — We recruited 216 persons between 35 and 70 years of age diagnosed with type 2 diabetes ≥1 year. Intervention groups of eight participants and eight support persons were randomly assigned to the compressed or extended conditions. The interventions differed in total number of contact hours over the yearlong intervention period, with the major difference being the number of support group sessions held. The same information provided in the educational sessions of the extended intervention was compressed into fewer sessions, thus providing more information during each group meeting.

RESULTS — The interventions were not statistically different in reducing HbA_{1c}; however, both were effective. A "dosage effect" of attendance was detected with the largest HbA_{1c} reductions achieved by those who attended more of the extended intervention. For individuals who attended ≥50% of the intervention, baseline to 12-month HbA_{1c} change was −0.6 percentage points for the compressed group and −1.7 percentage points for the extended group.

CONCLUSIONS — Both culturally competent diabetes self-management education interventions were effective in promoting improved metabolic control and diabetes knowledge. A dosage effect was evident; attending more sessions resulted in greater improvements in metabolic control.

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Twenty-one percent of the U.S. population lives in states bordering Mexico, and >33% of these individuals live in medically underserved border communities characterized by extreme poverty, pollution, deprivation, poor health, and diminished quality of life (1). Sixty percent of Hispanics, predominantly Mexican Americans who have the lowest rates of insurance coverage of any group, live in border states (2), and diabetes and related morbidity and mortality rates are highest among these border residents (3–6).

Traditional approaches to managing diabetes in the U.S. have been perceived by Mexican Americans, in some instances, as culturally insensitive and, thus, have been ineffective (7). We designed and tested nonpharmacological, culturally competent, community-based diabetes self-management interventions in Starr County, a Texas-Mexico border community in which 98% of the residents are Mexican American (8). Promoting attendance at lifestyle programs, i.e., ensuring an adequate "dosage" of the intervention, is a challenge, particularly in underserved groups who may lack transportation and who tend to live chaotic lives, with frequent financial, health, and personal crises. Mexican Americans value social networks, and women are expected to provide health care for family, relatives, and friends, often at the expense of their own personal health.

Considering the data from the initial Starr County diabetes self-management study that indicated a maximum benefit at 6 months, we developed a less intensive "compressed" intervention involving 22 contact hours over 12 months as opposed to the original "extended" intervention involving 52 contact hours over 12 months. The same information provided in the extended intervention was compressed into fewer sessions, thus providing more information during each group meeting. Another major difference in the interventions involved support group sessions, which were reduced from 14 in the extended intervention to 3 in the compressed. Here, we report our analyses of the compressed compared with the original extended intervention and describe the "dosage effects" on three primary clinical outcomes: HbA_{1c}, fasting blood glucose (FBG), and diabetes knowledge. We hypothesized that there would be no sig-

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Abbreviations: FBG, fasting blood glucose; HLM, hierarchical linear model.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

nificant differences in study outcomes at 3 and 12 months among subjects in the two interventions. Similar effects would support the utility of the shorter intervention, which would be easier to integrate into clinical and community settings.

RESEARCH DESIGN AND METHODS

— The study site, Starr County, has been described previously (8–11). Significant barriers to health result from high unemployment (24.4% compared with 4.6% for the state), low per capita income ($8,225 compared with $25,369 for the state), and some of the state's poorest housing, as well as from being medically underserved (ratio of population per physician 7,657:1 compared with 3,789:1 for the state; registered nurse ratio 851:1 compared with 159:1 for the state) (12–14).

A sample of 216 participants was selected from rosters of ongoing genetic studies. Based on our previous studies, we estimated that a total of 170 subjects (85 each for the compressed and extended conditions) provided power of 80% for detecting a medium between-group effect size on HbA_{1c} (15). Oversampling by 30% helped to account for potential attrition, although the retention in our previous Starr County studies was excellent, at 90% on average. Inclusion criteria included the following: *1*) 35–70 years of age and *2*) diagnosed with type 2 diabetes (two verifiable FBG results ≥140 mg/dl or taking or having taken insulin or hypoglycemic agents for ≥1 year). To capitalize on the cultural importance of family and social relationships, each subject was asked to identify a family member, preferably a spouse, first-degree relative, or close friend to participate. We excluded individuals if they were pregnant or had medical conditions for which changes in diet and walking were contraindicated (e.g., renal failure or previous amputation).

Six cohorts were recruited, and individuals were assigned to groups; 114 were allocated to compressed groups and 102 to extended groups. To control for between-group differences in socioeconomic status and foster group support between weekly sessions, each group was organized within a specific area of the county and then randomly assigned to either compressed or extended conditions. Four groups of eight subjects and their support people constituted each cohort; two groups were randomly assigned to the compressed intervention and two to the extended. The same process occurred every 3 months until 23 groups were enrolled. Intervention groups began immediately after baseline data collection, and further data were collected as cohorts reached 3-, 6-, 12-, 24-, and 36-month examination dates. Attendance at data collection sessions averaged 82%. Only 10 of the 216 study participants who attended baseline data collection sessions were considered true dropouts because they did not return for any additional sessions. Physicians were notified by letter that their patients were participating. We sent test results alerting them of high values, using pre-established thresholds for blood pressure, glucose, and lipids. Before the study, written informed consent was obtained according to procedures approved by two university institutional review boards.

Description of the culturally competent interventions

The original yearlong extended intervention is described elsewhere (8,9). Teams of bilingual Mexican-American nurses, dietitians, and community workers from Starr County or other border areas were assigned to lead the interventions. Both interventions compared in this study were offered in community-based sites throughout Starr County: schools, churches, adult day care centers, and health clinics. Cultural competence was operationally defined in both interventions as employing the preferred language, integrating cultural dietary preferences, emphasizing social activities and family participation, and holding open nonjudgmental discussions of cultural health beliefs and practices. For both interventions, social support was emphasized by including participation from family members or friends (including their participation in all measurements), fostering social relationships with other group participants, and encouraging communication between participants and intervention team members.

The redesign of the original intervention (extended) into a shorter version (compressed) was informed by focus groups held with participants of the previous Starr County study (16). The initial intervention was an intensive 1-year series of 12 weekly 2-h sessions on nutrition, home glucose monitoring, physical activity, and other self-management topics, followed by 14 2-h support group sessions to promote behavioral change through problem solving and goal setting. The compressed intervention involved eight weekly 2-h educational sessions followed by support sessions strategically held at 3, 6, and 12 months. Both interventions covered similar information, but the time spent on some topics differed. All participants received their usual diabetes care, if any, provided by local physicians or clinics, which for some individuals was obtained in Mexico.

Measurements

Measures of intervention effectiveness were similar to those used previously (8): demographics (age, sex, age of diabetes diagnosis, etc.); acculturation (the degree to which persons of foreign origins adopt American customs) (17); family, medical, and medication history; diabetes knowledge; health beliefs; HbA_{1c}; FBG; blood pressure; BMI; cholesterol; and triglycerides (10,11). Here, we report the results of three primary clinical outcomes: HbA_{1c}, FBG, and diabetes knowledge. HbA_{1c} was analyzed at The University of Texas-Houston (Glyc-Affin Ghb; Isolab, Akron, OH). FBG (10-h fasting) was performed in the research field office with a desktop glucose analyzer (YSI model 2300 STAT PLUS glucose and lactate analyzer; Yellow Springs Instruments, Yellow Springs, OH). The Spanish-language knowledge instrument was based on national standards and written to facilitate reading aloud to subjects (Küder-Richardson reliability ≥0.80) (18).

Statistical analysis

We compared the interventions with a prospective, quasi-experimental, repeated-measures, nested design. For measures spanning 12 months, incomplete data, which, if ignored, can lead to biased results, precluded use of standard statistical procedures (19). To handle missing data in the longitudinal analyses, we applied hierarchical linear models (HLMs) by which nonrandomly missing data were handled by including indicators of missing data patterns (20–22). In addition to adjusting for baseline differences, all analyses tested the main effects for age (years), intervention (compressed or extended),

Table 1—*A profile of subjects upon admission to the study*

Characteristics	Compressed	Extended	Total
n	114	102	216
Sex (women/men)	69/45	61/41	130/86
Age (years)	49.6 ± 7.6	49.6 ± 8.2	49.6 ± 7.9
Age at diagnosis of diabetes (years)	44.4 ± 8.3	44.6 ± 9.2	44.5 ± 8.7
BMI (kg/m^2)	32.2 ± 5.8	32.9 ± 8.3	32.5 ± 7.1
Diabetes medication modalities (*n*)	94	95	
Oral agents (%)	78.0	81.1	
Insulin (%)	5.3	6.3	
Oral and insulin (%)	4.3	1.1	
Other (%)	2.1	1.1	
None (%)	10.6	10.5	
Acculturation (range 1–4)	0.9 ± 0.9	1.2 ± 1.3	1.0 ± 1.1
Preferred language: Spanish (%)	74	68	71
Language at home: Spanish (%)	84	66	76
First language: Spanish (%)	97	92	95
Read no or little English (%)	56	55	56
Comorbidities: history of			
Myocardial infarction (%)	5.3	7.8	6.5
Angina (%)	4.4	5.9	5.1
Stroke (%)	0	2.9	1.4
Hypertension (%)	35.1	36.3	35.6
High cholesterol (%)	37.7	40.2	38.9
Gallbladder surgery (%)	11.4	15.7	13.4

Data are means ±SD, unless otherwise indicated. In acculturation, 4 = high acculturation.

sex, number of hours of intervention attendance, and all two-way interactions. To better understand the nature of the intervention effects, dosage effects in particular, we conducted a series of two (compressed versus extended) by two (high attendance, that is, above the median, versus low attendance, that is, below the median) ANCOVAs. For the comparisons at 3 months, the point at which the educational portion of both interventions ended, baseline measures were treated as covariates. The 3-month measures were treated as covariates for the 12-month analyses, reflecting the time period during which support sessions were held.

RESULTS

Baseline results

Subjects were similar to those in our previous studies—predominantly female, obese, ~50 years of age on average, and in poor metabolic control (Table 1). Language-based acculturation was low, indicating a Spanish language preference. With the exception of "language spoken at home," there were no statistically significant differences between the compressed and extended groups on any baseline measure. The number of individuals treated with insulin did not differ significantly at baseline between groups. Hypertension and high cholesterol were the most commonly reported comorbidities.

Three- and 12-month results

All measures decreased from baseline to 3 months (immediate effects) and from baseline to 12 months (longitudinal effects) in both intervention conditions; the baseline to 12-month change in HbA_{1c} for the compressed group was −0.7%, whereas for the extended group, the change was −1.0% (Table 2). An initial analysis, based on the intention-to-treat principle, involved a two-group (compressed and extended) ANCOVA for the 12-month scores, with the baseline as the covariate. Data from all participants, regardless of intervention attendance, were included in the analyses. No significant differences between programs were found for any of the outcomes.

HbA_{1c}. HLM analyses indicated that at 3 months, no intervention group differences in HbA_{1c} levels were detected. Men on average had lower HbA_{1c} levels ($t = -3.11$, $P = 0.002$), and those men who had greater attendance at the educational component of the intervention achieved lower HbA_{1c} levels, regardless of intervention type. For change in HbA_{1c} over

Table 2—*Primary outcomes*

Outcome measure in program	Baseline	3 months	12 months	Baseline to 3-month change	Baseline to 12-month change
HbA_{1c}					
Compressed	11.8 ± 3.4 (114)	10.9 ± 2.8 (94)	11.1 ± 3.2 (96)	−0.9*	−0.7†
Extended	11.5 ± 3.5 (102)	11.0 ± 3.3 (94)	10.5 ± 3.0 (89)	−0.5†	−1.0*
FBG					
Compressed	192.1 ± 64.4 (114)	164.9 ± 54.1 (94)	179.7 ± 61.6 (97)	−27.2‡	−12.4†
Extended	190.5 ± 68.3 (102)	177.5 ± 61.1 (94)	173.8 ± 63.6 (89)	−13.0*	−16.7†
Knowledge					
Compressed	14.7 ± 3.4 (114)	16.0 ± 3.3 (93)	16.0 ± 3.4 (97)	1.3‡	1.3‡
Extended	14.9 ± 3.2 (102)	16.2 ± 3.0 (94)	16.4 ± 3.0 (89)	1.3‡	1.5‡

Data are means ±SD (*n*) based on the total sample ($n = 216$). Knowledge range: 0–24. Data in table reflect means of all individuals who provided data at that measurement point. Significance levels reflect paired comparisons for those individuals for whom we have the measure at both measurement points (baseline + 3 months, baseline + 12 months). *$P = 0.01$; †$P = 0.05$; ‡$P = 0.001$.

Table 3—*Trend analysis of significant intervention effects: ANCOVA analyses controlling for baseline measures*

		M_{adj}: Intervention attendance†						
		Experimental group: compressed		Control group: extended		*P*		
Outcome measure	Measurement time*	Low	High	Low	High	Intervention	Attendance	Intervention by attendance interaction
HbA_{1c}								
	3-month	11.6 ± 3.1 (33)	10.5 ± 2.6 (61)	11.8 ± 3.8 (43)	10.5 ± 2.6 (51)	0.71	<0.001	0.74
	12-month	10.8 ± 3.5 (21)	11.3 ± 3.1 (62)	11.3 ± 3.0 (37)	10.0 ± 2.5 (46)	0.30	0.40	0.05
FBG								
	3-month	175.2 ± 57.9 (33)	159.6 ± 51.5 (61)	195.8 ± 65.4 (43)	163.6 ± 46.2 (51)	0.09	<0.001	0.20
	12-month	181.1 ± 75.7 (21)	178.5 ± 54.4 (63)	183.8 ± 76.0 (37)	165.0 ± 40.7 (46)	0.15	0.23	0.45
Diabetes knowledge								
	3-month	15.2 ± 2.8 (32)	16.3 ± 3.5 (61)	15.8 ± 3.0 (43)	16.6 ± 2.9 (51)	0.51	0.02	0.67
	12-month	12.6 ± 6.4 (26)	15.0 ± 5.1 (67)	13.3 ± 6.2 (44)	15.7 ± 5.5 (50)	0.73	0.007	0.96

Data are means ±SD (*n*). *3-month measurement is evaluation of educational component of the intervention, controlling for baseline differences in outcome variable; 12-month measure is evaluation of support group component, controlling for 3-month differences in outcome variable; †M_{adj} = adjusted mean, based on baseline mean.

time, the interaction between intervention and attendance suggested that for the extended intervention, greater overall attendance at both the educational and support sessions was related to greater reductions in HbA_{1c} over time ($B = -0.08$, $t = -6.51$, $P < 0.001$). Attendance did not moderate change in levels for the compressed intervention.

FBG. HLM analyses indicated that at 3 months, no group differences in FBG levels were detected. On average, those who attended a greater percentage of the educational component of the intervention showed relatively lower levels of FBG at 3 months, regardless of intervention type. Similarly, at 12 months, those who attended a greater percentage of both the educational and support sessions showed lower FBG levels regardless of intervention type. On average, greater attendance was related to lower levels across all individuals ($B = -1.06$, $t = -2.21$, $P < 0.05$).

Diabetes knowledge. HLM analyses indicated that at 3 months, no group differences in knowledge were detected. Attendance at both educational and support sessions was related to greater knowledge levels at 12 months. At 12 months, knowledge was in general positively related to the number of hours of attendance ($B = 0.08$, $t = 5.26$, $P < 0.001$). On average, knowledge scores did not change between months 3 and 12 when the focus was on providing support groups ($B = 0.01$, $t = 0.57$, $P = 0.569$).

Intervention attendance. To explore the interaction effects of intervention and attendance on clinical outcomes, analyses were conducted on low versus high attendance (Table 3). There were no statistically significant main effects for type of intervention, i.e., no program differences. There were statistically significant main effects for attendance for all three outcomes at 3 months but only for knowledge at 12 months. Consistent with the analyses reported above, there was an intervention by attendance interaction for HbA_{1c} at 12 months.

The baseline to 12-month change in HbA_{1c} for those who attended ≥50% of the intervention sessions was −0.6 percentage points for the compressed group (12-month HbA_{1c} = 11.0%) and −1.7 percentage points for the extended group (12-month HbA_{1c} = 9.2%).

We also compared the baseline to 12-month change in HbA_{1c} of top 10% (n = 18) achievers in reducing HbA_{1c}, using these individuals as "role models," with individuals who were least successful (n = 18). "Top achievers" attended, on average, 57% of sessions, whereas the lowest group attended 37%. Top achievers reduced HbA_{1c} levels by −6 percentage points (baseline HbA_{1c} = 16.3%; 12-month HbA_{1c} = 10.2%), compared with an increase of 4 percentage points in the lowest group (baseline HbA_{1c} = 10.0%; 12-month HbA_{1c} = 14.2%). The post hoc analyses of adjusted means showed that the difference between the low attendance and high attendance groups was statistically significant for those receiving the extended intervention (11.3 vs. 10.0, $P \leq 0.05$) but not for those who had received the compressed intervention (10.8 vs. 11.3). The intervention effect was statistically significant for the high attendees (11.3 vs. 10.0, $P \leq 0.05$) but not for the low attendees (10.8 vs. 11.3).

Study participants who attended the least number of intervention sessions (n = 30) verbalized an intention to participate but attended few sessions due to the following reasons: too busy with work (n = 8), illness in the family/serve as family caregiver (n = 7), felt too "lazy" to go/"didn't make the time" (n = 5), needed transportation (n = 5), migrating (n = 2), too busy at home (n = 2), moved (n = 2), and never told about the class (n = 1). (Some individuals gave more than one reason.)

Costs of the two interventions were estimated based on the following assumptions: *1*) monitors and strips are covered by insurance, *2*) educational materials are a one-time purchase at the outset of the project, and *3*) free community-based sites are available. (During our intervention studies, numerous sites in the community were provided at no cost. Overhead charges added by for-profit organizations that might offer such interventions are not included, but some programs charge an overhead of ≥50%.) Based on personnel and food demonstration costs only (not including indirect costs), the following cost comparisons were made. The compressed intervention results in a 60% cost savings over the extended intervention.

Extended care (nurse and dietitian at sessions 1–12):

- 12 educational sessions at \$120/session = \$1,440
- 14 support group sessions at \$70/session = \$980
- Food: \$25/session for 26 sessions = \$650
- Total: \$3,070/8 diabetic subjects per group = \$384/person

Compressed care (nurse or dietitian at each session):

- 8 educational sessions at \$70/session = \$560
- 3 support group sessions at \$70/session = \$210
- Food: \$25/session for 11 sessions = \$275
- Total: \$1,045/8 diabetic subjects per group = \$131/person

CONCLUSIONS — Health problems of border residents present unique challenges created by rapid population growth; substandard housing with lack of water, sewage systems, and paved roads; lack of health care access caused by a need to travel long distances to obtain services and lack of transportation; poverty that precludes paying for physician visits or recommended treatment; and individuals who speak only Spanish (23). Mexican Americans living on the U.S. side of the border obtain >50% of their health care in Mexico due to lower costs, greater accessibility, and perceptions of greater effectiveness (24). We designed an intervention by taking into account this sociocultural context (12).

Because there was little guidance from previous research regarding the appropriate "dosage" of educational and behavioral interventions for impoverished, non–English-speaking populations, we originally developed an intensive intervention but measured outcomes at regular intervals to determine the point of maximum intervention impact (8,11). The purpose of this study was to modify our original yearlong program into a shorter, more resource efficient strategy that would be more easily integrated into clinical settings.

Discussions of diabetes self-management always lead to concerns about costs, particularly when one is promoting the need for increasing intervention dosage. Typical diabetes education programs range from 4 to 15 h of education over a 2- to 3-month time period and cost between \$95 and \$125 per 1-h session; group instruction costs slightly less (25). In some instances, complete diabetes education services can cost \$200 or more per person (26). The most intensive Starr County intervention (extended) was considerably more intensive than typical programs: 52 h over a 12-month time period. The intervention also cost significantly less: \$7.39 per person per hour. In either the extended or the compressed intervention, the cost was estimated to be less than that associated with a year's prescription of a single medication and is not excessive when the costs of diabetes morbidity and mortality are considered.

We have consistently found that our self-management interventions are more effective for participants with very elevated glucose levels, such as in Starr County, where the average baseline values have been ~12%, rather than those with more average levels of 8–9%. This factor limits the generalizability of our interventions. We demonstrated the effectiveness of culturally competent diabetes self-management education; but study participants, on average, did not achieve the national HbA_{1c} target of ≤7%. The initial Starr County study showed a 1.4–percentage point difference in HbA_{1c} at 6 months between experimental and control groups, although the mean HbA_{1c} levels at all measurement points remained >10% (8). Data from the study reported here indicated a decrease in both interventions, but the best result (HbA_{1c} = 9.2%) occurred in the extended intervention for individuals who received the maximum "dose," that is, those who attended ≥50% of the intervention sessions. Although these levels are higher than the national target, these improvements significantly improve health. ". . . [F]or every 1–percentage point decrease in HbA_{1c}, there is a 35% reduction in the risk of microvascular complications, a 25% reduction in diabetes-related deaths, a 7% reduction in all cause mortality, and an 18% reduction in combined fatal and nonfatal myocardial infarction" (3). Nonpharmacological, community-based lifestyle interventions, such as those we developed in Starr County, offer a way for individuals to decrease or delay diabetes morbidity and mortality, can be implemented in any clinical or community setting, and do not rely on access to traditional health care services (27).

Behavioral interventions are as important to the clinical care of persons with diabetes as are medications. Because of doubts about compliance with behavioral interventions, such programs frequently are not valued nor are they included in any comprehensive diabetes management strategy. Most health professionals would agree that changing health behavior is complex and difficult; however, based on the findings of this study, past failures in improving health behaviors may have been the result of inadequate intervention dosage. Diabetes self-management programs should be prescribed in a manner similar to diabetes medications, that is, provide the desired "dose" and then "reinoculate" at key intervals, such as annually or at other times when the disease status changes (acquiring a new complication or a change in medication). For individuals similar to participants of the Starr County study, persons who come from impoverished backgrounds and who have few resources, we recommend the extended program of 52 h over 12 months, with reinoculation at least annually. However, there are no generally accepted, experimentally supported strategies for reinoculation after an initial intervention. The Medicare benefit includes an annual 4-h reinoculation in diabetes self-management education and nutrition counseling, but the efficacy of this strategy has not been tested. Interventions designed to maintain long-term benefits of self-management programs must be tested in future research to determine the most cost-effective reinoculation strategies.

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