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Dosage Effects of Diabetes Self-Management Education for Mexican Americans: The Starr County Border Health Initiative

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Abstract

Objective—To compare 2 diabetes self-management interventions designed for Mexican Americans: "extended" (24 hours of education, 28 hours of support groups) and "compressed" (16 hours of education, 6 hours 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 \geq 1 year. Intervention groups of 8 participants and 8 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 \geq 50% of the intervention, baseline-to-12-month HbA_{1c} change was -0.6%-age points for the "compressed" and -1.7%-age points for the "extended."

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 more than 1/3 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 non-pharmacologic, 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 — that is, 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 intervention to 3 in the "compressed." Here, we report our analyses of the "compressed" compared to 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 significant differences* in study outcomes at 3 and 12 months between 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 to 4.6% for the State), low per capita income (\$8,225 compared to \$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 to 3,789:1 for the State; registered nurse ratio 851:1 compared to 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, 90% on average. Inclusion criteria were: (1) 35 to 70 years of age; and (2) diagnosed with type 2 diabetes ([a] 2 verifiable FBG results of \geq 140 mg/dl or [b] taking *or* have taken insulin *or* hypoglycemic agents for \geq 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, 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 8 subjects and their support people constituted each cohort; 2 groups were randomly assigned to the "compressed" intervention and 2 to the "extended." The same process occurred every 3 months until 23 groups were enrolled. Intervention groups began immediately after baseline date collection and further date

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 "drop outs"; that is, 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. Prior to the study, written informed consent was obtained according to procedures approved by 2 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, non-judgmental 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 re-design 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 one-year, series of 12 weekly 2-hour sessions on nutrition, home glucose monitoring, physical activity, and other self-management topics, followed by 14 2-hour support group sessions to promote behavioral change through problem solving and goal setting. The "compressed" intervention involved 8 weekly 2-hour 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, gender, 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 knowledge. HbA_{1c} was analyzed at The University of Texas-Houston (Glyc-Affin Ghb, Isolab Inc., Akron, Ohio). FBG (10 hours fasting) was performed in the Research Field Office with a desktop glucose analyzer (YSI Model 2300 STAT PLUS Glucose and Lactate Analyzer). The Spanish-language knowledge instrument was based on national standards and written to facilitate reading aloud to subjects (Küder-Richardson reliability \geq . 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 (HLM) by which non-randomly 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," "extended"), gender, 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, "low attendance," that is, below the median) ANCOVA. 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, approximately 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 co-morbidities.

3- 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%-age points, while for the "extended" group, the change was -1.0%-age points (Table 2). An initial analysis, based on the "intention to treat principle," involved a 2-group ("compressed," "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.

HbA1_c—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=.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 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=-.08, t=-6.51, p<.001). Attendance did not moderate change in levels for the "compressed" intervention.

Fasting Blood Glucose (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

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of intervention type. On average greater attendance was related to lower levels across all individuals (B=-1.06, t=-2.21, p<.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=.08, t=5.26, p<.001). On average, knowledge scores did not change between the 3rd and 12th months when the focus was on providing support groups (B=.01, t=0.57, p=.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, that is, no program differences. There were statistically significant main effects for attendance for all 3 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 \geq 50% of the intervention sessions was -0.6%-age points for the "compressed" group (12-month HbA_{1c} = 11.0%) and -1.7%-age 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, while the lowest group attended 37%. "Top achievers" reduced HbA_{1c} levels by -6%-age points (baseline HbA_{1c} = 16.3%; 12-month HbA_{1c} = 10.2%), compared to an increase of +4%-age 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 difference between the low attendance and high attendance groups was statistically significant for those receiving the "extended" intervention (11.3 vs. 10.0, $p \le .05$) 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, $p \le .05$) 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:

Too busy with work (8)

Illness in the family/serve as family caregiver (7)

Felt too "lazy" to go/"didn't make the time" (5)

Needed transportation (5)

Migrating (2)

Too busy at home (2)

Moved (2)

Never told about the class (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% or more.) 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."

Extended Care" (nurse and dietitian at sessions 1–12)	*****
2 educational sessions at \$120/session =	\$1440
4 support group sessions at \$70/session =	980
Food: \$25/session for 26 sessions =	650
Total: \$3070/8 diabetic subjects per group =	\$ 384/person
Compressed Care" (nurse or dietitian at each session)	
educational sessions at \$70/session =	\$ 560
support group sessions at \$70/session =	210
Food: \$25/session for 11 sessions =	275
Total: \$1045/8 diabetic subjects per group =	\$ 131/person

CONCLUSIONS

Health problems of border residents present unique challenges created by rapid population; 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 more than 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).

Since 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 the study we report here 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 hours of education over a 2- to 3-month time period and cost between \$95 and \$125 per one-hour 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 hours 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 approximately 12%, rather than those with more average levels of 8% to 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 \leq 7%. The initial Starr County study showed a 1.4%-age point difference in HbA_{1c} at 6 months between experimental and control groups, although the mean HbA_{1c} levels at all measurement points remained above 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 \geq 50% of the intervention sessions. Although these levels are higher than the national target, these improvements significantly improve health. "... for every 1%-age 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). Non-pharmacologic, 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. Due to 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 selfmanagement 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 hours 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-hour "reinoculation" in diabetes self-management education and nutrition counseling, but 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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A FTOLLE OF SUDJECTS UPOIL AUTILISSION TO THE STUDY. Characteristics	Compressed $n = 114 (69F \& 45M)$	(69F & 45M)	Extended $n = 102$ (61F & 41M)	61F & 41M)	Total <i>n</i> =216 (130F & 86M)	0F & 86M)
	М	SD	Μ	SD	Μ	SD
Age in years	49.6	7.6	49.6	8.2	49.6	<i>9.</i> 7
Age at diagnosis of diabetes	44.4	8.3	44.6	9.2	44.5	8.7
BMI	32.2	5.8	32.9	8.3	32.5	7.1
Diabetes medication modalities Oral agents Insulin Oral & Insulin Other	(n = 94) 78.0% 5.3% 4.3% 2.1%		(n = 95) 81.1% 6.3% 1.1% 1.1%			
Acculturation (range: 1–4) Preferred Language: Spanish Language at Home: Spanish First Language: Spanish Read No or Little English	0.9 74% 84% 56%	6.0	 68% 65% 55%	1.3	1.0 71% 95% 56%	1.1
Co-Morbidities: History of5.3%MI4.4%Angina4.4%Stroke0Hypertension35.1%High cholesterol11.4%Gallbladder surgery11.4%	5.3% 4.4% 0 33.1% 11.4%		7.8% 5.9% 2.9% 40.2% 15.7%		6.5% 5.1% 1.4% 35.6% 13.4%	

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Table 2	Standard Deviations for Primary Outcomes (C="compressed"; E="extended")	me Measure Program Baseline 3 Months 12 Months Baseline to 3-Mo. Change Baseline to 12-Mo. Change	Based on Total Sample $(n=216)$	C 11.8±3.4 ($n=114$) 10.9±2.8 ($n=94$) 11.1±3.2 ($n=96$) -0.9^{**} -0.7^*	HbA _{1c} E $[1.5\pm3.5 (n=102)]$ 11.0±3.3 $(n=94)$ 10.5±3.0 $(n=89)$ -0.5^{*} -1.5^{**}	C [192.1±64.4 (n =114) 164.9±54.1 (n =94) 179.7±61.6 (n =97) -27.2 ^{***} -12.4 [*]	FBG E 190.5 ± 68.3 ($n=102$) 177.5 ± 61.1 ($n=94$) 173.8 ± 63.6 ($n=89$) -13.0^{**}	C [1/ 7+3 / (n-11/1] 16 (1+3 3 (n-03) 16 (1+3 / (n-07) 15 (n+07)
	eans ± Standard Deviat	Outcome Measure			HbA _{1c}		FBG	

Note: 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 which we have the measure at both measurement points (baseline + 3 months, baseline + 12 months).

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16.4±3.0 (n=89)

16.2±3.0 (n=94)

14.9±3.2 (n=102)

Щ

Knowledge

 $p \leq 05$

 $p \le 01$

 $^{***}_{p\leq 001}$

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Trend Analysis of Significant Intervention Effects: ANCOVA Analyses Controlling for Baseline Measures Table 3

				Intervention by attendance interaction	.74	.05	.20	.45	.67	96.
			Significance (p)	Attendance	<.001	.40	<.001	.23	.02	.007
				Intervention	.71	.30	.09	.15	.51	.73
INICASULOS	Control Group 'Extended'	INTERVENTION ATTENDANCE	High Attendance	M _{adj}	$10.5\pm 2.6(51)$	$10.0\pm 2.5(46)$	$163.6\pm 46.2(51)$	$165.0\pm40.7(46)$	$16.6\pm 2.9(51)$	$15.7\pm5.5(50)$
US, ALVEO VA AILAI yes COMPUTING TOL DASCING INCASHIES			Low Attendance	M _{adj} **	$11.8\pm 3.8(43)$	$11.3\pm 3.0(37)$	$195.8\pm 65.4(43)$	$183.8\pm76.0(37)$	$15.8\pm3.0(43)$	$13.3\pm6.2(44)$
A MILLING COLUMN	Experimental Group "Compressed"	INTERVENTION ATTENDANCE	High Attendance	M _{adj} **	$10.5\pm 2.6(61)$	$11.3\pm3.1(62)$	$159.6\pm 51.5(61)$	$178.5\pm 54.4(63)$	$16.3\pm3.5(61)$	$15.0\pm 5.1(67)$
LILLUIS, MINCO V			Low Attendance	M _{adj}	$11.6\pm 3.1(33)$	$10.8\pm 3.5(21)$	$175.2\pm 57.9(33)$	$181.1\pm75.7(21)$	$15.2\pm 2.8(32)$	$12.6 \pm 6.4(26)$
	Measurement Time				3-Month	12-Month	3-Month	12-Month	3-Month	12-Month
TIGHT WHATS OF STRUCTURE THE ACTIVITY FILE	Outcome Measure					HbA_{1c}	Fasting	Blood Glucose		Diabetes Knowledge

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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

** Madj = adjusted mean (based on baseline mean)