

Strong in Body and Spirit

Lifestyle intervention for Native American adults with diabetes in New Mexico

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OBJECTIVE— To determine the effects of a culturally appropriate diabetes lifestyle intervention for Native Americans on risk factors for complications of diabetes.

RESEARCH DESIGN AND METHODS— A nonrandomized, community-based diabetes intervention trial was conducted in three Native American sites in New Mexico from 1993–1997. Participants were assigned to intervention or control based on community of residence. Intervention sessions were held ~6 weeks apart over ~10 months. The intervention was delivered in site A in family and friends (FF) groups ($n = 32$); site B received the same intervention in one-on-one (OO) appointments ($n = 39$); and site C received usual medical care (UC) ($n = 33$) (total participants, $n = 104$). Primary change in HbA_{1c} level was assessed at 1 year.

RESULTS— Adjusted mean change in HbA_{1c} value varied significantly across the three arms at 1 year ($P = 0.05$). The UC arm showed a statistically significant increase in adjusted mean HbA_{1c} change (1.2%, $P = 0.001$), whereas both intervention arms showed a small nonsignificant ($P > 0.05$) increase in the adjusted mean change (0.5% and 0.2% for FF and OO arms, respectively). The increase was statistically significantly smaller in the combined intervention arms (0.4%) compared with the UC arm (1.2%, $P = 0.02$).

CONCLUSIONS— Lifestyle intervention has the potential to substantially reduce microvascular complications, mortality, and health care utilization and costs if the change is sustained over time.

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Many Native American tribes suffer from a high and increasing prevalence of type 2 diabetes; among some Native American adults, the prevalence is >50% (1). Moreover, Native Americans suffer higher prevalence of many of the complications associated with diabetes (2–8). The high prevalence of type 2 diabetes, combined with a poorer prognosis, contributes to a disproportionately high and increasing diabetes-related mortality rate among Native

American populations. In New Mexico, diabetes-related mortality increased by 564 and 1,110% for Native American men and women, respectively, from 1958 to 1994 (9,10).

One approach to reducing the disproportionate burden of type 2 diabetes is to develop interventions directed toward reducing the risk factors for the complications of this chronic disease. At the cornerstone of diabetes interventions are diet and physical activity; however, their roles

frequently have been dismissed as impossible to achieve by researchers, clinicians, and patients (11,12). Therefore, interventions focus on clinical treatments, such as hypoglycemic medications, which have been shown to reduce microvascular complications in persons with type 2 diabetes (13). Interventions that emphasize a combination of diet, physical activity, and clinical treatments may have the greatest potential to reduce the risk factors for diabetes-related complications (14). There is a paucity of effective diabetes lifestyle interventions for Native Americans with diabetes (15,16).

In response to this need, the Native American Diabetes Project: Strong in Body and Spirit, a culturally appropriate lifestyle intervention, was designed and developed (17). Strong in Body and Spirit was a nonrandomized community-based lifestyle intervention, conducted in combination with usual clinical intervention, with a goal of evaluating effectiveness of a lifestyle intervention specifically targeted for Native American adults with diabetes. The hypothesis was that involvement in a culturally appropriate lifestyle intervention in conjunction with comprehensive clinical care would positively affect glyce-mic control.

RESEARCH DESIGN AND METHODS

Study design

The nonrandomized community-based intervention was developed and conducted from August 1993 through July 1997 in eight Rio Grande Pueblo communities in New Mexico. All eight communities are served by three Indian Health Service (IHS) clinics and had an expressed interest in testing this new community-based intervention model. Selection into the intervention was based on participant's community of residence and was not based on self-selection. Site A received the intervention in family and friends (FF) groups; site B received the same intervention in one-on-one (OO) appointments; and site C agreed to serve

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Abbreviations: FF, family and friends; IHS, Indian Health Service; OO, one-on-one; UC, usual medical care.

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

as the control and receive usual medical care (UC) from IHS and delayed intervention 1 year later.

Participants were identified through local diabetes registries by way of an agreement with the IHS. All Native American women and men with type 2 diabetes, aged ≥ 18 years, who were physically and mentally able and who resided in one of the eight communities were eligible to participate in the intervention. Trained Native American interviewers invited potential participants by telephone and/or in person. All participants gave written informed consent and the study protocol was approved by the Institutional Review Boards of the IHS, the University of New Mexico, and the participating tribes.

Chart audit

A 100% review of the IHS medical records of the entire population of persons with diabetes served by the three IHS centers in 1994 ($n = 514$) and 1996 ($n = 517$) was conducted. A standardized review protocol previously described by IHS Diabetes Headquarters Program was used (18). Covariates collected in the chart review from the IHS clinics included duration of diabetes and time since diagnosis in years and months. Medication use was recorded as diet alone, oral agent, insulin, and oral agent plus insulin (combined with the insulin group for purposes of analyses). Additional laboratory data included total cholesterol, triglyceride, and creatinine measured as mg/dl. Proteinuria was defined as having 1+ (30 mg/dl) or more protein in a urine dipstick test during the past year. Hypertension was defined as diagnosis of hypertension or use of medication for hypertension, prescribed as documented in the medical record. Cerebrovascular accident or stroke and myocardial infarction or heart attack were defined as history of one of these events or use of medication to prevent such events. Amputation was defined as amputation of either a toe, foot, or leg. Nephropathy was defined as serum creatinine level ≥ 2.0 mg/dl, and retinopathy was defined as background, proliferative, or macular edema documented by dilated fundoscopic examination. Laser treatment was defined as history of undergoing laser photocoagulation for retinopathy.

Intervention outcome measures

Measures were obtained at preintervention and postintervention visits, each separated by ~ 1 year and administered at the same time of year. Trained staff members used a standardized protocol to obtain demographic and lifestyle variables using standardized in-person interview methods, measured and recorded weight to the nearest half-pound, and measured blood pressure using the American Heart Association standard protocol (19). HbA_{1c} is measured as percentage of hemoglobin that is glycosylated (expressed as HbA_{1c}%). HbA_{1c} was measured using a DCA 2000 analyzer (Bayer, West Haven, CT) using standardized protocol as reported previously (20). Validity and reliability of the DCA 2000 were assessed on a random sample of subjects before the intervention. The correlation was 0.993 and the mean absolute relative difference between the DCA 2000 and high-performance liquid chromatography system was 1.2%.

Intervention

A nonrandomized community-based diabetes lifestyle intervention was used in each of the two intervention arms. Ideally, randomization to intervention arms within communities would be best. However, this was not acceptable to the communities involved and probably would have been affected by contamination, which would have resulted in bias. One intervention arm received culturally appropriate diabetes educational materials, skill building, and social support provided within a family and friends (FF) format, and the second intervention arm received the same information provided in a one-on-one (OO) format (17).

The intervention was designed and developed using community preferences and principles of social learning theory and consisted of five sessions: "Get more exercise!"; "Eat less fat!"; "Eat less sugar!"; "Together we can!"; and "Staying on the path!" (21,22). Through focus group sessions, the community requested that the intervention include traditional Native American values, Native American foods, information about exercise and diet, and videos featuring Native Americans. To incorporate traditional Native American values, the community coordinator (G.E.P.) wrote stories that were used throughout the intervention, which is a traditional method of Native American learning. Native American foods and Na-

tive American individuals engaging in healthy lifestyle behaviors were featured in videos. The intervention sessions were held ~ 6 weeks apart and were conducted over a 10-month period from 1995 to 1996 and have been described in more detail elsewhere (17,23,24). Briefly, the information provided in the intervention included written materials as well as food and physical activity demonstrations. The FF arm of the intervention included activities that were designed to encourage social interaction and discussion about diabetes among members of the group. During the intervention, a mentor led the participants through the written materials and encouraged them to discuss and share their stories about living with diabetes. In addition, participants in the FF arm joined in physical activities as a group and shared a healthy meal. The same written materials given to the participant of the FF arm were presented to the participants in the OO arm by a mentor in individual sessions.

The participants of the UC control group followed their usual schedules of IHS clinic visits and activities and accessed medical services provided by IHS. All participants received comprehensive diabetes care, which included IHS minimum standards of diabetes care, and professional and patient education; however, the participants in the UC arm did not receive culturally specific intervention materials (18,25).

Statistical analysis

Demographic and preintervention levels of clinical and laboratory variables were compared between intervention arms using either an analysis of variance for continuous variables or χ^2 or Fisher's exact tests for discrete variables. The analyses of the primary study end points of HbA_{1c} level and weight were conducted for all evaluable participants (i.e., subjects with baseline and follow-up measures). Analysis of covariance was used to test the hypothesis of intervention differences in HbA_{1c} level and weight. During planning, two measurements of HbA_{1c} were recorded 1 year apart. In addition to the planned covariates of sex, age, duration of diabetes, medication use, and two preintervention determinations of annual change in HbA_{1c}, factors found to be significantly different at baseline across the intervention arms were included as covariates in all subsequent analyses. For

Table 1—Selected preintervention demographic and clinical characteristics of evaluable participants

	FF	OO	UC	P†
Demographic and clinical				
n	32	39	33	
Men	9 (28%)	10 (26%)	3 (9%)	0.12
Women	23 (72%)	29 (74%)	30 (91%)	
Age (years)	60.2 (12.1)	59.9 (13.4)	60.2 (11.8)	0.99
Duration of diabetes (years)	8.1 (5.3)	8.3 (6.4)	10.0 (6.6)	0.35
HbA _{1c} (%)	8.3 (1.9)	9.2 (2.3)*	7.9 (2.0)*	0.03
Weight (lb)	174.6 (35.4)	172.2 (37.2)	168.9 (33.8)	0.81
BMI (kg/m ²)	31.0 (5.6)	31.2 (6.8)	32.0 (6.1)	0.78
Diastolic blood pressure (mmHg)	80 (9)	81 (12)	78 (10)	0.45
Cholesterol (mg/dl)	199 (51)	218 (50)	193 (43)	0.10
Triglycerides (mg/dl)	224 (147)	290 (214)	214 (154)	0.21
Creatinine (mg/dl)	1.3 (0.9)	1.1 (0.5)	1.0 (0.9)	0.35
Medication use and treatments				
Diet	5 (16%)	6 (15%)	11 (33%)	0.12
Insulin	2 (6%)	10 (26%)	7 (21%)	0.10
Oral agents	25 (78%)*	23 (59%)*	15 (46%)*	0.03
Laser treatment	2 (6%)	2 (5%)	3 (9%)	0.78
Complications				
Hypertension	59*	33*	56*	0.05
Proteinuria	39	31	43	0.60
Retinopathy	19	33	25	0.41
Nephropathy	10	13	9	0.87
Myocardial infarction	6	5	9	0.89
Cerebrovascular accident	3	0	6	0.29

Data are n, frequency (%), or mean (SD). *Statistically significantly different by Tukey's studentized range (honestly significant difference); †P values obtained using χ^2 test for hypertension, proteinuria, retinopathy, nephropathy, laser treatment; analysis of variance for age, duration, HbA_{1c}, weight, BMI, diastolic blood pressure, cholesterol, triglycerides, and creatinine; and Fisher's exact test for myocardial infarction and cerebrovascular accident.

purposes of analysis, the second measurement of preintervention HbA_{1c} served as the baseline value before the intervention. The change in HbA_{1c} level between the first and second measurements served as a covariate because it reflected possible changes due to clinical practice. Statistical testing was performed at the 0.05 level (two-sided P values when two groups were compared). All statistical analyses were performed using SAS software (SAS Institute, Cary, NC) (26).

RESULTS

During the planning year, a total of 514 Native American individuals with diabetes were listed in the IHS diabetes registry. A total of 206 (40%) eligible men and women volunteered to participate in interviews at the beginning of the planning year. During the planning year, 47 participants (23%) withdrew before receiving the intervention; the remaining 159 participants underwent the preintervention

interview (77%). A total of 42 participants (26%) dropped out of the study during the intervention and did not undergo postintervention assessment, and 13 participants did not have information on covariates for analyses (8%); the total number of evaluable participants was 104 (65%).

Using the chart audit databases, evaluable participants (n = 104) were generally representative of the target population (n = 514) and did not differ by duration of diabetes, HbA_{1c} level, weight, blood pressure, cholesterol, triglyceride or creatinine levels, history of medication use, hypertension, retinopathy, nephropathy, proteinuria, laser treatment, myocardial infarction, or cerebrovascular accident (data not shown). Compared with the nonparticipants, the evaluable participants included more women (79 vs. 58%, P = 0.001) and were older (60 vs. 57 years, P = 0.04). Participants who did not complete the intervention were

generally representative of evaluable participants. More women than men and more obese than nonobese participants were evaluable; those leaving the study did not differ by age, duration of diabetes, HbA_{1c} level, weight, diastolic blood pressure, cholesterol, triglyceride or creatinine levels, history of medication use, hypertension, retinopathy, nephropathy, proteinuria, laser treatment, myocardial infarction, or cerebrovascular accident.

The preintervention characteristics for the 104 evaluable participants are summarized in Table 1. Statistically significant differences existed between the three arms at preintervention in HbA_{1c} level; the participants in the OO arm had the highest HbA_{1c} values, and the participants in the UC arm had the lowest HbA_{1c} values (P = 0.03). The proportion of participants receiving oral agents was significantly lower in the UC arm than in either of the intervention arms (P = 0.03). Hypertension was significantly more common in the participants in the FF and UC arms than in the OO arm (P < 0.05) and was as a covariate in all subsequent analyses.

The results of the intervention on HbA_{1c} level and weight across the three intervention arms at 1 year, for participants who completed the study, are summarized in Fig. 1. Adjusted mean change in HbA_{1c} value varied significantly across the three arms at 1 year (P = 0.05). The UC arm showed a statistically significant increase in adjusted mean HbA_{1c} change (1.2% [0.4], P = 0.001), whereas both intervention arms showed a small, non-significant (P > 0.05) increase in the adjusted mean change (0.5% [0.3] and 0.2% [0.3] for the FF and OO arms, respectively). The increase was statistically significantly smaller in the combined intervention arms (0.4% [0.2]) compared with the UC arm (1.2% [0.4], P = 0.02). Weight decreased by 2.0 lb (1.5) in the FF arm and 1.8 lb (1.5) in the OO arm and increased by 1.7 lb (1.8) in the UC arm; however, these differences were not statistically significant (P = 0.14). The combined intervention arms were compared with the UC arm. Weight decreased by 1.9 lb (1.2) in the combined intervention arm, compared with the increase of 1.7 lb (1.8) in the UC arm, a difference that was statistically significant (P = 0.05).

The postintervention change in adjusted mean diastolic blood pressure and

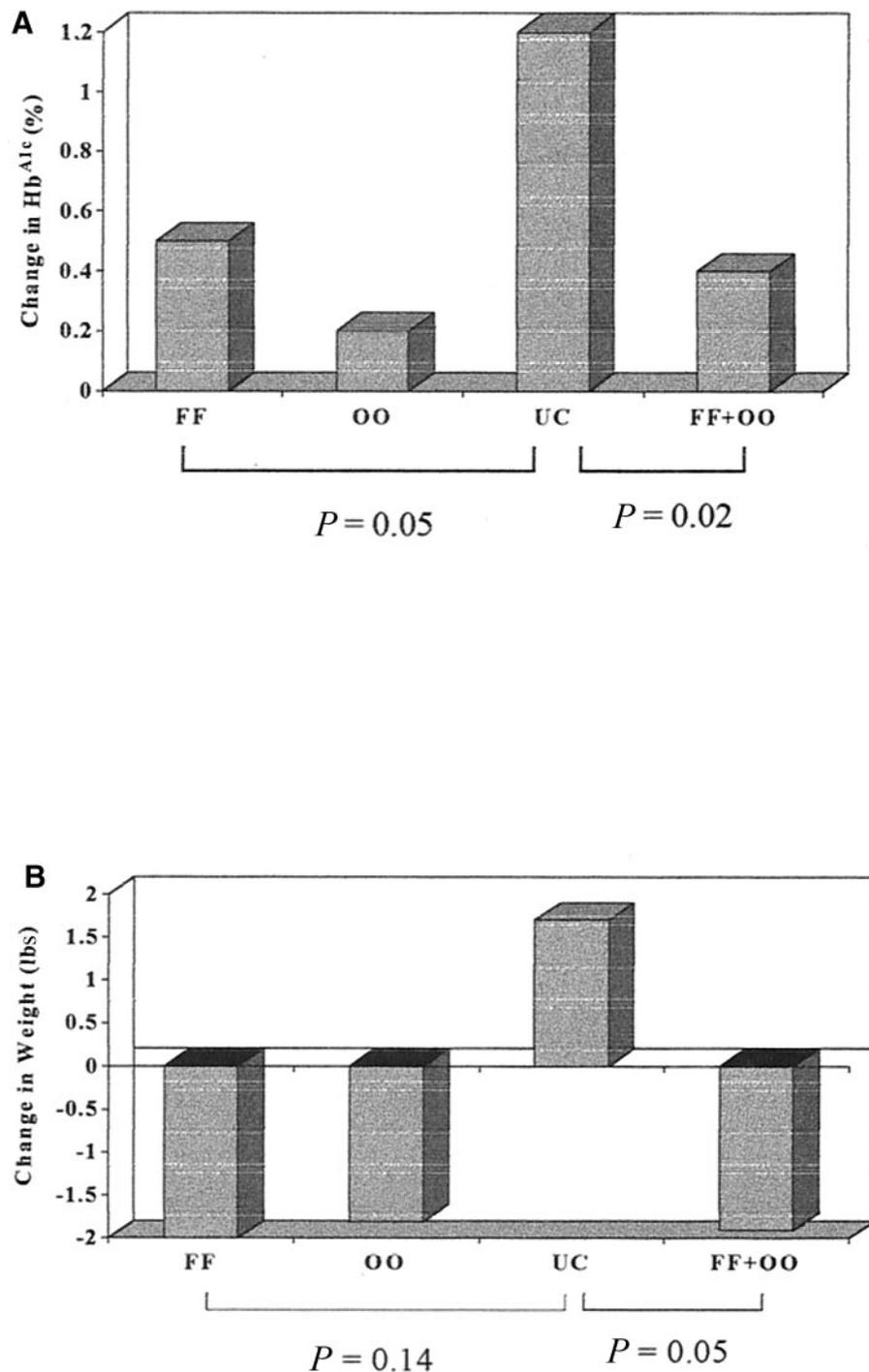


Figure 1—Postintervention change in adjusted mean HbA_{1c} for FF and OO intervention arms and the UC control arm at 1 year (A), and change in adjusted mean weight over the intervention period for the combined intervention arms (FF+OO), FF, OO, and UC at 1 year (B).

serum lipid levels are summarized in Table 2. Diastolic blood pressure decreased by 6 mmHg in the FF arm of the intervention and remained essentially unchanged in the OO and UC arms. This difference across the three arms was statistically sig-

nificant ($P = 0.02$); however, when we compared the combined results of the intervention arms with the results of the UC arm, there was no statistically significant difference ($P > 0.05$). Cholesterol and triglyceride levels also decreased across the

three arms of the intervention; however, this decrease in lipid levels was not statistically significant across the three arms or between the combined intervention arms compared with the UC arm ($P > 0.05$).

CONCLUSIONS

Our primary finding from this community-based intervention was that participants in the intervention had significant benefit in glycemic control and weight at 1 year compared with the UC control group after adjusting for covariates. Because HbA_{1c} level has been shown to be predictive of morbidity and mortality, the intervention has the potential to substantially reduce microvascular complications, mortality, and health care utilization and costs if the change can be sustained over time (13,27,28).

Our findings are consistent with a number of studies and trials that show the efficacy of lifestyle interventions in improving glycemic control (15,29–31). Even though overall HbA_{1c} level increased, we observed an absolute difference of 0.8% in HbA_{1c} level between the combined FF and OO arms versus the UC arm. Although the factors are not fully understood, the magnitude of increase in HbA_{1c} in this study (1.2%) in 1 year was equivalent to that observed during a 6-year period in the conventional care group of the U.K. Prospective Diabetes Study (13). Additional support for the effectiveness of lifestyle interventions among Native Americans with diabetes is illustrated by a retrospective evaluation of 30 participants with type 2 diabetes who participated in a community-based exercise intervention of weekly group aerobic exercises and significantly lowered their fasting blood glucose levels and weight (16,31,32). The results of the present study provide more evidence that participation in a community-based lifestyle intervention may result in improvement in glycemic control among Native Americans with type 2 diabetes. We observed a very small change in weight. The intervention was designed to improve participants' overall risk factor profiles and focused on making healthy changes (e.g., eating less sugar and fat, more exercise) and was not a weight-loss program but used weight as an objective measure of effectiveness.

There are few data on the sustainability of lifestyle changes after community interventions in minority communities.

Table 2—Postintervention change in adjusted mean diastolic blood pressure, cholesterol, and triglyceride levels for FF and OO intervention arms and UC control arm and combined intervention arms at 1 year

	FF	OO	UC	FF + OO versus UC	P value across three arms	P value between FF + OO and UC
n	32	39	33			
Diastolic blood pressure (mmHg)	−6.5 (2.0)	−0.4 (1.7)	−0.3 (2.1)	−3.4 (1.4)	0.02	0.25
Cholesterol (mg/dl)	−22 (11)	−20 (11)	−10 (16)	−21 (8)	0.79	0.50
Triglycerides (mg/dl)	−178 (78)	−48 (48)	−69 (63)	−68 (48)	0.21	0.81

Data are n (mean).

Agurs-Collins et al. (29) conducted a 3-month randomized study of 64 overweight African-American men and women aged 55–79 years with type 2 diabetes. Subjects were randomized to either a weight-loss and exercise program or usual care (29). The intervention consisted of 12 weekly group sessions, 1 individual session, and 6 biweekly group sessions. At the end of 6 months, there were significant differences in mean HbA_{1c} values (−2.4% compared with the usual care control group). However, there was no further follow-up after 6 months and whether the beneficial effects were sustainable was not addressed by the study. In the present study, a positive effect of a lifestyle intervention was observed at 1 year and suggests that changes may be maintained over a longer term. Five sessions of Strong in Body and Spirit were conducted (one session every 6 weeks); the sessions stressed making small changes over time and did not emphasize weight loss. The Strong and Body and Spirit model is different from shorter, more intensive interventions and may be more realistic for a community intervention.

How might one account for the effects of the intervention? First, because the risk factors for preventing or delaying the onset of diabetes complications are complex and interdependent, it may be that interventions that include comprehensive clinical and culturally appropriate lifestyle interventions have the greatest potential to reduce the risk factors associated with diabetes complications. The Steno type 2 randomized trial in Denmark is one of the few interventions that has evaluated a realistic combined clinical and lifestyle intervention. The trial was designed to determine the effect of a combined clinical and lifestyle intervention as compared with standard pharmacological intervention (14). Participants in the multifactorial intervention had significantly

lower rates of progression to nephropathy, neuropathy, and retinopathy than those in the standard pharmacological intervention. Therefore, a combined clinical and lifestyle intervention in individuals with type 2 diabetes may be more effective than either intervention alone.

Second, the intervention materials were designed and developed with input from focus group sessions of Native American community members to determine their preferences (17,23,24). The intervention used traditional Native American story telling to convey information about diabetes. Traditional Native American foods and physical activities were included in the intervention and videos featured Native American individuals engaging in healthy lifestyle behaviors. Therefore, the intervention content was culturally relevant and contained values pertinent to the Native American communities (17,23,24). The intervention used traditional Native American educational messages that were more culturally appropriate and more effectively communicated than standard diabetes education materials; this may have improved the effectiveness of the intervention. In a 12-month pilot trial of 95 obese Native American men and women without diabetes, Narayan et al. (15) compared a structured activity and diet intervention with a less structured intervention that emphasized Pima culture. Participants of the Pima culture intervention had less of an increase in glucose levels than the more structured group and gained less weight. These results lend support to the usefulness of interventions that use culturally appropriate materials.

Our study has a number of limitations as well as strengths. This study was not a randomized study and, therefore, may be subject to selection bias. A randomized protocol was not acceptable to the communities involved. Due to close kinship ties within communities, randomization

would likely have been affected by contamination, which would result in bias. Although preintervention differences in the study arms were adjusted for, the study may be confounded from unmeasured or poorly measured covariates. We observed increasing HbA_{1c} levels over the study period among participants in the UC arm. The IHS uses minimum standards of diabetes care based on American Diabetes Association standards of care, and all participants received care from the IHS. Although there are differences in clinical practices, it is unlikely that the UC arm received poor care. It is possible that unmeasured or poorly measured factors could account for the difference. There was a relatively small sample size to precisely estimate the magnitude of effects between the intervention arms. Nearly 40% of the population of people with diabetes participated in the study, and there were few differences between evaluable participants and the target population, as well as those who dropped out of the study. Therefore, the results are likely to be generalizable to community members with diabetes. Evaluable participants received the full content of the intervention, and missed sessions were taught during make-up sessions at the participant's convenience. Because only people from Rio Grande Pueblo Native American communities were included in this study, the findings may not be generalizable to other tribes. More than 70% of participants who started the intervention completed it, but participants in the UC group were more likely to drop out of the study; it may be that they had grown impatient with the wait for the intervention. More women and older participants were evaluable, suggesting that the intervention may be more amenable to these individuals. Future studies may need to develop interventions that appeal to men and younger people with diabetes. An important strength of the study is that the

intervention was well accepted in these Native American communities, as documented previously (24).

Because the prevalence of type 2 diabetes in Native Americans is projected to increase, there is an urgent need for the development and dissemination of more interventions that are both culturally appropriate and clinically comprehensive, including emphasis on self-management of diabetes care, to prevent and/or delay complications of diabetes in this high-risk population.

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