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Recruitment and effectiveness by cohort in a case management intervention among American Indians and Alaska Natives with diabetes

Katherine A. Pratte,[1] Janette Beals,[2] Ann Johnson,[2] Ann Bullock,[3] Spero M. Manson,[2] Luohua Jiang,[1] and the Special Diabetes Program for Indians Healthy Heart Project Demonstration Project*

[1]Department of Epidemiology, University of California Irvine, School of Medicine, 205B Irvine Hall, Irvine, CA 92697, USA

[2]Centers for American Indian and Alaska Native Health, Colorado School of Public Health, University of Colorado Anschutz Medical Campus, 13055 East 17th Ave, Aurora, CO 80045, USA

[3]Division of Diabetes Treatment and Prevention, Indian Health Service, 5600 Fishers Lane, Rockville, MD 20857, USA

Correspondence to: Luohua Jiang, lhjiang@uci.edu

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Abstract

In real-world settings, eligible populations and intervention effectiveness for a translational intervention likely vary across time. To determine the optimal strategies for effective large-scale implementation of evidence-based interventions, it is critical to investigate these potential variabilities. The purpose of this study is to evaluate whether patient characteristics and intervention effectiveness differed by year of enrollment in a multiyear evidence-based translational intervention. The Special Diabetes Program for Indians Healthy Heart (SDPI-HH) Demonstration Project is an intensive case management intervention designed to reduce cardiovascular disease risk among American Indians and Alaska Natives with diabetes. SDPI-HH participants recruited from 2006 through 2008 were included. Baseline characteristics were compared by year of enrollment. We also evaluated the differences in improvements in clinical and behavioral risk factors for cardiovascular disease among participants recruited in different years. The baseline characteristics of the three cohorts significantly differed in demographics, diabetes duration, health behaviors, level of motivation, and clinical measures. Improvements in 13 clinical and behavioral outcomes also differed by enrollment year with the 2006 cohort having the greatest number of significant improvements and the highest rates of participation and retention. Further investigation into the ways to modify the intensive case management model to address differences in levels of motivation and participation is warranted to improve the management of chronic disease in Indian health. Given the evolving nature of translational initiatives of this kind, our analysis results highlight the need to understand and adapt during the natural progression of health behavioral interventions.

Keywords

Translational research, Intensive case management, Effectiveness, Recruitment

Implications

Practice: To optimize participant retention and intervention effectiveness, practitioners of future translational projects of an evidence-based behavioral intervention may need to modify the intervention delivery approach in later enrollment years to address the differences in participants' motivation, maintenance of the quality of intervention delivery, and other system or staff-level factors that may dilute effectiveness.

Policy: Policymakers who want to decrease the risk of cardiovascular disease among patients with diabetes should consider how their eligible population characteristics might change over time in large-scale implementation initiatives of the intensive case management model and provide advice on how to modify the delivery of care accordingly.

Research: Future research is needed into ways to modify the delivery of intensive case management intervention to address different levels of motivation and participation. Meanwhile, various delivery-setting factors that could impact sustained effectiveness and participant involvement, such as staff turnover, funding instability, and competing priorities should be assessed to sustain intervention effectiveness and participant involvement in future similar translational efforts.

INTRODUCTION

In the USA, the risk of developing diabetes among American Indians and Alaska Natives (AI/ANs) is 2.3 times that of non-Hispanic whites [1]. In addition, complications of diabetes such as heart disease, stroke, and kidney failure are among the leading causes of death among AI/ANs [2], with cardiovascular disease (CVD) now being the leading cause of mortality. Early detection and treatment of risk factors associated with these complications can reduce the risk of CVD development and progression [3].

In 1997, with increasing awareness of the severe diabetes epidemic in AI/AN populations, Congress established the Special Diabetes Program for Indians (SDPI), calling on the Indian Health Service (IHS) to direct funding for diabetes treatment and prevention. In 2003, Congress increased funding levels and directed the IHS to establish a competitive grant program. This program allowed IHS, tribal, and urban Indian health programs to compete for funding to

participate in the development and implementation of two translational interventions: one for diabetes prevention among AI/ANs with prediabetes, the other for CVD risk reduction in those with diabetes. In late 2004, the successful grantee sites and key members of the IHS Division of Diabetes Treatment and Prevention began a collaborative process to develop and implement the demonstration projects.

The chronic care model, developed to make routine ambulatory care for patients with chronic diseases proactive [4], was chosen as the framework for the SDPI Healthy Heart Project (SDPI-HH, the CVD risk reduction arm of SDPI). In particular, using case management methods, SDPI-HH grantees decided upon a clinic and team-based approach that consisted of (a) assessment of each patient's CVD risk and development of an individualized treatment plan; (b) disease management through physical exams and treatment goals for hypertension, dyslipidemia, smoking cessation, and hyperglycemia; and (c) self-management education based on the Honoring the Gift of Heart Health (HGHH) curriculum developed for addressing CVD risk among AI/ANs with diabetes [5]. The clinic-based intensive case management activities were based on what was then current national American Diabetes Association [6] and IHS evidence-based standards of care for patients with type 2 diabetes [7].

Since previous research had proven the efficacy of the intensive case management approaches [8–11], the SDPI-HH effort was considered translational in nature, where current evidence-based treatments were implemented on a large scale in 30 diverse healthcare settings; the effectiveness of the intervention was then assessed. In contrast to rigorously controlled randomized clinical trials in which patient populations are carefully defined, the evaluation of translational initiatives seeks to assess the effectiveness of interventions proven efficacious in diverse patient populations. Indeed, previous analyses of SDPI-HH data have shown significant improvements between baseline and a 1-year follow-up in the primary outcome variables of HbA1c, blood pressure, and lipid control among all participants recruited over a 3-year period, presenting evidence for the overall effectiveness of SDPI-HH [12].

In addition to an evaluation of overall effectiveness, the multiyear longitudinal structure of the SDPI-HH lends itself to evaluating changes over time. In real-world settings, the eligible participant populations likely vary across time; for example, more motivated and/or targeted patients may enroll early. Accordingly, these patients may have a higher level of readiness to change their behaviors and may perceive greater potential program benefit than patients enrolled in later years. Indeed, SDPI site staff reported observing changes in their participants' motivation and characteristics over the first few years of recruitment. These observations suggest it is important to investigate the association of changes in participant motivation and characteristics with intervention outcomes. To determine the optimal strategies for effective large-scale implementation of evidence-based interventions, it is critical to investigate continued effectiveness as an intervention rolls out to large, diverse populations [13]. Only by understanding whether changes in patient characteristics occur over time, which may lead to changes in intervention effectiveness and suggest the need to consider correspondingly new approaches to motivate patients, we are able to fully address the challenges in scaling up successful interventions to regional, national, or international levels [13].

The goal of the current study is to compare the outcomes of intensive case management intervention among SDPI-HH participants recruited in different years (2006–2008). In particular, we examine baseline differences in target population, rates of participation and retention, and intervention effectiveness across different years of enrollment. These data provide a valuable opportunity to evaluate program implementation over time with findings that may inform future, similar large-scale translational intervention.

MATERIALS AND METHODS

Data collection

IHS funded 30 grant programs under SDPI-HH, consisting of 7 IHS, 21 tribal, and 2 urban Indian health programs. Most programs commenced enrollment in January 2006; the few participants (n = 50) who started at the end of 2005 are included in the 2006 cohort. Participants were recruited from each site's diabetes registry, medical database, and/or community activities. Participants had to be AI/AN (based on eligibility to receive IHS or tribal services), have a previous or new diagnosis of diabetes, and be at least 18 years of age. Exclusion criteria included current pregnancy and end-stage renal disease on dialysis. Based on provider judgment, those with active alcohol or substance abuse, under current cancer treatment, or having unstable CVD were excluded.

Baseline assessments were typically obtained within 1 month before the initiation of intensive case management. Annual assessments were conducted to measure changes in clinical, behavioral, and psychosocial measurements. Each baseline or annual assessment included medical history regarding the date of diabetes diagnosis; physical measurements of height, weight, and waist circumference; clinical measurements of blood pressure and clinical laboratory test results of HbA1c and lipids; smoking status, aspirin use, and minutes of physical activity in the prior month. At each assessment, participants also completed a questionnaire to report psychosocial characteristics and dietary choices. During the annual assessments, participants reported whether they had participated in any HGHH classes in the

last year. Throughout the project, case managers recorded the number of case management visits participants had attended. In this study, the baseline and first annual data from SDPI-HH participants enrolled in the first 3 years of the project (i.e., 2006–2008) were compared.

The SDPI-HH protocol was approved by the institutional review board of the University of Colorado Anschutz Medical Center and the National IHS institutional review board. When required, grantees obtained approval from other entities, such as tribal review boards, which oversaw their program. In addition, participants provided written informed consent and Health Insurance Portability and Accountability Act authorization.

Measures

Baseline demographic characteristics contrasted across the 3 years of enrollment included participants' gender, age, educational attainment, employment status, marital status, and annual household income as reported in the baseline questionnaire. Clinical characteristics included years since diabetes diagnosis, BMI (body mass index), waist circumference, blood pressure, HbA1c, and lipids (high-density lipoprotein [HDL], low-density lipoprotein [LDL], and triglyceride) measured at clinical assessment. At baseline, case managers obtained medical history data on date of diabetes diagnosis. The number of years since diabetes diagnosis was determined by the number of years between baseline assessment date and the date of diagnoses. To evaluate whether a participant was newly diagnosed with diabetes at enrollment, a variable determining whether a participant had been diagnosed for a year or less at baseline was created.

Certain baseline behavioral characteristics were also compared among different cohorts, including smoking status, aspirin use, physical activity, dietary choices, and stages of change. Smoking status was defined as current smoker (yes/no). Aspirin use was defined as using aspirin daily or taking an anticoagulant (yes/no), whether no contraindication for use was reported. To assess the physical activity level for each participant, at baseline and annually, staff members asked participants to report the average minutes of physical activity per week in the previous month.

Details about the dietary choice variables are described elsewhere [14]. Briefly, participants were asked to recall the intake of 18 different types of foods over the last 30 days using a self-administered food frequency questionnaire. The frequency of each type of food was reported as (i) less than once a month, (ii) 1–3 times a month, (iii) about once a week, (iv) 2–3 times per week, (v) about once a day, and (vi) more than once a day. The healthy food score was constructed by averaging the intake frequency of 6 healthy foods, while the unhealthy food score was the mean intake frequency of 12 unhealthy foods.

Stages of change theory suggest that those who move from "precontemplation" to "action" stages will be more likely to make the changes necessary for better health outcomes [15–18]. To evaluate readiness to change behaviors among SDPI-HH participants, baseline stages of change for the following behaviors were compared: (i) *Exercise*. Asked about their plans for regular exercise (defined as 150 min per week of planned activities to increase physical fitness) [15]; (ii) *Diet*. Focusing upon the avoidance of high-fat foods [19]; and (iii) *Weight Control*. Assessed weight loss intent and activities [20].

Intervention outcomes of the SDPI-HH project were improvements in both clinical and behavioral risk factors for CVD between baseline and Year 1 annual assessments. Clinical outcomes included BMI, waist circumference, blood pressure, HbA1c, and lipids. Behavioral outcomes included aspirin use, smoking status, dietary choices, and physical activity. Goals for behavioral outcomes were set as smoking cessation, daily use of aspirin, and ≥150 min/week of physical activity. Treatment to target for clinical outcomes were defined as BMI <30 kg/m^2, waist circumference <40 inches for males and <35 inches for females, blood pressure <130/80 mmHg, A1c <7%, HDL >40 mg/dl for males and >50 mg/dl for females, LDL <100 mg/dl, and triglycerides <150 mg/dl.

Program participation was measured by the mean number of case management visits during the first year among all participants who enrolled and by the percentage of participants completed a Year 1 assessment. Additional measures of participation are the mean number of case management visits and percentage of participants attending any HGHH classes among participants with a Year 1 assessment.

Statistical analyses

The three cohorts for comparison in this study were defined as those recruited in years 2006, 2007, and 2008, respectively. Baseline characteristics of the three cohorts were compared using chi-square tests for categorical variables and ANOVA for normally distributed continuous variables. For non-normally distributed continuous variables (years with diabetes, minutes of physical activity per week in the last month, and triglycerides), a ranked transformed analysis of variance was used [21]. For pairwise comparisons among the three cohorts, a Bonferroni adjustment of multiple comparisons was used to determine significant differences between a pair of means. All analyses were conducted in SAS version 9.3 (SAS Institute Inc., Cary, NC).

Linear mixed models were used to estimate mean changes for each of the normally distributed outcomes between baseline and the Year 1 assessment. Each mixed model included a binary time indicator

variable (baseline vs. Year 1), a categorical cohort variable (2006, 2007, 2008), and an interaction between time and cohort as fixed effects. All models also included random intercepts at the individual level to model participant-level heterogeneity [22]. For highly skewed continuous variables (e.g., minutes of physical activity), a generalized linear mixed model with a Poisson distribution and a log link function was employed to estimate the rate ratio of Year 1 versus baseline. To evaluate changes in the proportions of participants obtaining treatment goals, a generalized linear mixed model with a binary distribution and a logit function was used. In all generalized linear mixed models, the same fixed effects were included as well as random residuals to model overdispersion. Estimate and contrast statements were included to estimate changes between baseline and Year 1 assessments in each cohort year and to evaluate differences in these changes between cohorts. Sensitivity analyses were conducted after adding age, gender, time since diabetes diagnosis, and psychological distress into the regression models. The main parameters of interest did not change much in these models. Therefore, we presented the results of the simpler models as the main findings of this study.

RESULTS

Baseline characteristics

By the end of 2008, 2910 diabetes patients had enrolled in the SDPI-HH and completed a baseline assessment. Table 1 shows the baseline differences among the three enrollment year cohorts. The number of enrolled participants decreased over the 3 years. Compared with latter cohorts, the first cohort (2006) had a greater percentage of females, older participants, and had higher incomes. They also had diabetes for a longer period of time, a smaller proportion of newly diagnosed participants, lower diastolic blood pressure, and mean HbA1c but higher triglycerides. Regarding behavioral characteristics, the 2006 cohort consumed healthy foods more frequently, unhealthy foods less often, reported fewer minutes of weekly physical activity, were more likely to be in the maintenance stages for exercise and diet, and were less likely to be current smokers. In addition, Table 1 reveals no baseline differences among cohort years in the percentages of participants with goal attainment for clinical and behavioral outcomes, although the 2008 cohort had a marginally higher percentage meeting the A1c goal at baseline ($p = .0523$).

Intervention effectiveness

Table 2 presents improvements in clinical and behavioral outcomes by enrollment year for participants completing a Year 1 assessment. In general, the number of improvements in clinical and behavioral indicators decreased with each succeeding year of enrollment. Cohort 2006 achieved the highest rate of improvement with 11 out of 13 intervention outcomes statistically significant. The 2007 cohort obtained improvements in 10 outcomes while the 2008 cohort obtained improvement in only 7 outcomes. In 2006, only HDL and healthy diet choices did not significantly improve, while for the 2007 cohort no significant improvements were seen in systolic blood pressure, HDL, and minutes of physical activity. Unlike the earlier cohorts, the 2008 cohort did show a significant increase in mean HDL levels, but did not achieve significant improvements in BMI, waist circumference, systolic and diastolic blood pressure, triglycerides, or minutes of physical activity.

The changes in achieving intervention goals also varied by enrollment year and, in many cases, were consistent with the mean improvements (Table 2). The 2006 cohort had the greatest number of significant improvements in targeted goals among the three cohorts. These participants achieved significant changes in the proportions of attaining intervention goals for five outcomes: blood pressure, HbA1c, LDL, triglycerides, and physical activity. The 2007 cohort only achieved significant changes in the percentages of goal attainment for three goals: LDL, triglycerides, and physical activity. The 2008 cohort also had significant changes in the proportions of obtaining three goals: HbA1c, HDL, and triglycerides.

Table 2 statistically contrasts differences in intervention outcomes by cohort as well. For most of these changes, the differences when compared across cohorts were not statistically significant. However, the magnitude of the 2008 cohort's improvement in their mean HDL was greater than that of the other two cohorts ($p = .0001$). For LDL, the magnitude of change was similar in both 2006 and 2007 cohorts, but the reduction in 2007 cohort was greater than that in the 2008 cohort. Increase in physical activity in the 2006 cohort was significantly greater than those in the 2 succeeding years. In addition, 2006 cohort demonstrated greater success at Year 1 in attaining targeted goals than the latter two cohorts for physical activity and blood pressure, although there was no difference in the magnitude of change between 2006 and 2007.

Program participation

Table 3 presents data on participation over the 3 years of enrollment. The mean number of case management visits during the participant's first year differed based on enrollment year. Cohort 2008 had significantly fewer case management visits than cohorts 2006 and 2007 ($p < .0001$). The percentage of participants completing their Year 1 assessment decreased from the 2006 to 2007 to 2008 cohorts. Among the participants who completed their Year

Table 1 | Baseline demographics and clinical and behavioral characteristics by enrollment year

		Enrollment year (*N* = 2910)			
		2006 *n* = 1123	2007 *n* = 985	2008 *n* = 802	
Demographic characteristics	Category	*n* (%)	*n* (%)	*n* (%)	*p* Value
Gender	Male	348 (31.0)	353 (35.8)	311 (38.8)	.0013
	Female	775 (69.0)	632 (64.2)	491 (61.2)	
Age categories (years)	18 to <40	97 (8.6)	132 (13.4)	110 (13.7)	<.0001
	40 to <50	232 (20.7)	190 (19.3)	202 (25.2)	
	50 to <60	364 (32.4)	329 (33.4)	267 (33.3)	
	≥60	430 (38.3)	334 (33.9)	223 (27.8)	
Education	Post high school	558 (55.8)	495 (57.1)	354 (54)	.4953
	0–12 years	442 (44.2)	372 (42.9)	301 (46)	
Employment status	Employed	514 (53.7)	432 (53)	306 (50.7)	.0810
	Retired	195 (20.4)	147 (18)	103 (17.1)	
	Unemployed/student	249 (26)	236 (29)	195 (32.3)	
Marital status	Married or live together	542 (59.6)	432 (56.4)	314 (55.3)	.1036
	Separated, divorced, or widowed	258 (28.4)	224 (29.2)	158 (27.8)	
	Never married	109 (12.0)	110 (14.4)	96 (16.9)	
Annual household income	<15k	227 (26.3)	248 (33.4)	198 (35.5)	.0058
	15 to <30k	245 (28.4)	205 (27.6)	151 (27.1)	
	30 to <50k	228 (26.5)	175 (23.6)	128 (23.0)	
	≥50k	162 (18.8)	115 (15.5)	80 (14.4)	
Clinical characteristics		Mean (SD)	Mean (SD)	Mean (SD)	*p* Value
Years since diabetes diagnosis Median (5th; 95th percentile)		6.41 (0.35; 22.51)[c]	5.89 (0.22; 20.75)	5.89 (0.13; 21.28)[a]	.0028
Diabetes for less than a year		120 (11.3%)	134 (14.1%)	148 (19.5%)	<.0001
BMI (kg/m^2)		36.69 (7.83)	36.65 (8.01)	36.55 (8.42)	.9270
Waist circumference (Inches)		45.38 (6.50)	45.74 (6.89)	45.91 (6.97)	.2200
Systolic blood pressure (mm Hg)		128.81 (16.49)	128.74 (16.39)	128.72 (16.45)	.9912
Diastolic blood pressure (mmHg)		75.44 (9.88)[c]	76.12 (10.19)	76.82 (10.37)[a]	.0130
HbA1c (%)		7.57 (1.75)[b,c]	7.85 (2.00)[a]	8.06 (2.14)[a]	<.0001
HDL (mg/dl)		43.73 (11.88)	43.92 (11.87)	43.14 (11.18)	.3526
LDL (mg/dl)		98.31 (31.51)	99.74 (33.07)	97.63 (32.9)	.3744
Triglycerides (mg/dl) Median (5th; 95th percentile)		158 (74; 413)[b]	151 (69; 398)[a]	158 (71; 467)	.0420
Healthy diet score (range: 1–6)		3.62 (0.79)[b,c]	3.47 (0.81)[a]	3.47 (0.80)[a]	<.0001
Unhealthy diet score (range: 1–6)		2.58 (0.69)[b,c]	2.66 (0.75)[a]	2.71 (0.76)[a]	.0005
Physical activity (minutes per week) Median (5th; 95th percentile)		52.5 (0; 345)[b,c]	60.0 (0; 420)[a]	60 (0; 450)[a]	.0045
		2006 *n* = 1123	2007 *n* = 985	2008 *n* = 802	*p* Value
Behavioral characteristics		*n* (%)	*n* (%)	*n* (%)	
Physical activity goal (≥150 min per week)		257 (23.2)	275 (27.9)	258 (32.3)	<.0001
Stages of change for exercise	Pre/Contemplation	194 (19.6)	171 (20.7)	129 (20.1)	.0039
	Preparation	364 (36.8)	301 (36.4)	250 (38.9)	
	Action	180 (18.2)	199 (24.1)	137 (21.3)	
	Maintenance	251 (25.4)	155 (18.8)	126 (19.6)	

(Continued)

Table 1 | Continued

		Enrollment year (*N* = 2910)			
		2006 *n* = 1123	2007 *n* = 985	2008 *n* = 802	
Stages of change for diet	Pre/Contemplation	148 (15.7)	137 (18.0)	115 (19.2)	.0011
	Preparation	222 (23.6)	212 (27.8)	153 (25.5)	
	Action	240 (25.5)	201 (26.4)	179 (29.8)	
	Maintenance	332 (35.2)	212 (27.8)	153 (25.5)	
Stages of change for weight control	Pre/Contemplation	235 (23.7)	223 (26.8)	165 (25.5)	.4252
	Action	557 (56.2)	465 (56.0)	357 (55.3)	
	Maintenance	199 (20.1)	143 (17.2)	124 (19.2)	
Current smoker		199 (17.7)	203 (20.6)	198 (24.7)	.0010
Aspirin use		841 (78.0)	724 (76.1)	583 (75.1)	.3237
Clinical goal attainment at baseline		*n* (%)	*n* (%)	*n* (%)	*p* Value
BMI goal (<30 kg/m^2)		204 (18.2)	180 (18.3)	163 (20.3)	.4318
Waist goal (<40 inches male, <35 inches female)		72 (6.6)	69 (7.1)	65 (8.2)	.3800
Blood pressure goal (<130/80 mmHg)		486 (43.3)	420 (42.6)	334 (41.8)	.7913
HbA1c goal (<7%)		499 (44.4)	408 (41.5)	312 (39.0)	.0523
HDL goal (>40 mg/dl male, >50 mg/dl female)		367 (32.8)	320 (32.6)	273 (34.2)	.7355
LDL goal (<100 mg/dl)		594 (54.6)	509 (52.9)	443 (57.7)	.1369
Triglycerides goal (<150 mg/dl)		512 (45.7)	481 (48.9)	367 (45.8)	.2789

Values are estimated differences from a linear mixed model or a generalized mixed model. *BMI* body mass index; *HDL* high-density lipoprotein; *LDL* low-density lipoprotein; *SD* standard deviation.

[a]Significantly different from the mean of 2006 cohort at $\alpha = 0.017$ (based on Bonferroni correction for multiple comparisons).

[b]Significantly different from the mean of 2007 cohort at $\alpha = 0.017$ (based on Bonferroni correction for multiple comparisons).

[c]Significantly different from the mean of 2008 cohort at $\alpha = 0.017$ (based on Bonferroni correction for multiple comparisons).

1 assessment, significant differences were found among the three cohorts, with the 2007 cohort receiving the most case management visits and the 2008 cohort the fewest. Further, the percentages of participants attending an HGHH class during the first year of participation significantly differed by enrollment year ($p < .0001$), with cohort 2006 showing the highest rates.

DISCUSSION

SDPI-HH, as a translational intervention recruiting participants over several years, lends itself to the evaluation of baseline characteristics and continued effectiveness by cohort, defined here as year of enrollment. The results of this study demonstrate differences in cohort composition, degree of participation, and intervention effectiveness over time in this specific effort and suggest broader lessons for deploying translational initiatives of this nature.

Baseline participant characteristics differed across cohorts. Those enrolled in 2006 were older and had a longer duration of diabetes. A post hoc analysis, to aid in understanding these differences, showed that the first cohort had higher mean baseline diabetes knowledge and possibly a better understanding of the risk of CVD for diabetes patients. Therefore, they may be more motivated to make changes than those enrolled in the 2 latter years. This is demonstrated by the reduction, for subsequent cohorts, in the effectiveness on clinical and behavioral outcomes, and lower retention rates.

The 2006 cohort did not improve on two intervention outcomes: HDL and frequency of healthy food choices. The latter is due, perhaps, to the longer diabetes duration of this cohort, and, therefore, many had already changed to healthier food choices. This hypothesis is supported by the 2006 cohort reporting the highest value of baseline healthy diet score among the three cohorts. Cohorts 2007 and 2008, meanwhile, had greater numbers of newly diagnosed diabetes participants with lower baseline values for healthy food choices, with a resulting greater potential for improvement. Cohort 2006 also had the highest proportion of participants in the maintenance stage for stages of change in diet [20], a stage where the participants were expected

Table 2 | Changes in outcomes between baseline and Year 1 by enrollment year

	Enrollment year			
	2006 (n = 818)	2007 (n = 701)	2008 (n = 508)	
Changes in clinical outcomes	Δ Mean (SE)	Δ Mean (SE)	Δ Mean (SE)	Overall p value
BMI (kg/m^2)	−0.21 (0.08)*	−0.18 (0.09)*	−0.16 (0.10)	.93
Waist circumference (inches)	−0.29 (0.10)*	−0.44 (0.11)*	−0.22 (0.13)	.40
HbA1c (%)	−0.14 (0.06)*	−0.18 (0.06)*	−0.31 (0.07)*	.17
Systolic BP (mmHg)	−1.94 (0.62)*	−0.82 (0.67)	0.23 (0.78)	.09
Diastolic BP (mmHg)	−0.94 (0.38)*	−1.24 (0.41)*	−0.47 (0.47)	.46
HDL (mg/dl)	0.21 (0.29)[c]	−0.03 (0.31)[c]	1.88 (0.36)*[,a,b]	.0001
LDL (mg/dl)	−6.65 (1.06)*	−7.69 (1.14)*[,c]	−3.32 (1.34)*[,b]	.04
Triglycerides (mg/dl) (geometric mean and SE)	−1.08 (1.02)*	−1.05 (1.02)*	−1.03 (1.02)	.23
Changes in behavioral outcomes				
Healthy diet score	0.05 (0.03)	0.11 (0.03)*	0.10 (0.04)*	.32
Unhealthy Diet Score	−0.15 (0.02)*	−0.17 (0.03)*	−0.13 (0.03)*	.75
Physical activity (log estimate)	0.43 (0.07)[b,c]	0.09 (0.07)[a]	0.07 (0.8)[a]	.0007
(rate ratio of Yr 1:baseline estimate ± 95%CI)	1.54 (1.34, 1.77)*	1.10 (0.95, 1.27)	1.07 (0.91, 1.26)	
	Δ %	Δ %	Δ %	
Current smoker	−3.9%*	−2.9%*	−3.1%*	.37
Aspirin use	11.1%*[,c]	12.3%*[c]	7.6%*[,a,b]	.01
Changes in goal attainment	Δ %	Δ %	Δ %	
BMI goal (<30 kg/m^2)	1.2%	1.9%	1.8%	.88
Waist goal (<40 inches men, <35 inches female)	0.8%	1.9%	1.3%	.70
Blood pressure goal (<130/80 mmHg)	9.8%*[,c]	4.0%	1.1%[a]	.03
HbA1c goal (<7%)	5.3%*	1.9%	6.4%*	.21
HDL goal (>40 mg/dl male, >50 mg/dl female)	−0.4%	0.4%	5.0%*	.08
LDL goal (<100 mg/dl)	10.6%*	10.8%*	4.2%	.05
Triglycerides goal (<150 mg/dl)	4.7%*	5.5%*	5.1%*	.95
Physical activity goal (≥150 min/week)	16.1%*[,b,c]	6.6%*[,a]	2.2%[a]	<.0001

Values are estimated differences from a linear mixed model or a generalized mixed model. *BMI* body mass index; *HDL* high-density lipoprotein; *LDL* low-density lipoprotein; *SE* standard error.

[a]Significantly different from the mean of 2006 cohort at $\alpha = 0.017$ (based on Bonferroni correction for multiple comparisons).

[b]Significantly different from the mean of 2007 cohort at $\alpha = 0.017$ (based on Bonferroni correction for multiple comparisons).

[c]Significantly different from the mean of 2008 cohort at $\alpha = 0.017$ (based on Bonferroni correction for multiple comparisons).

*$p < .05$ for test with H_0: mean difference is equal to 0 (within-cohort changes).

to maintain their established healthy diet habits instead of achieving further improvements in their diet behaviors.

The lack of improvement in HDL was seen in cohort 2006 as well as 2007 even though both 2006 and 2007 cohorts had significant improvements in LDL and triglycerides levels. Cohort 2008 was the only cohort that obtained a significant mean improvement in HDL levels, along with a significant improvement in LDL levels but not triglycerides. The magnitude of LDL improvement in cohort 2008 was less than those achieved by the other two cohorts, however. The significant increase in HDL among 2008 participants could be due to HDL dysfunction in patients with poorly controlled or newly diagnosed diabetes [23]. Supporting this, the 2008 cohort also had the greatest level of HbA1c improvement; HbA1c reduction has been reported to improve HDL, but not LDL [24].

Participants in the 2008 cohort were recruited during the last year of the demonstration project funding and achieved the fewest improvements in outcomes, even while their baseline characteristics indicated considerable need. This lack of performance correlates with reduction in program participation. This may indicate a decrease in enthusiasm for the program, as funding came to an end, from not only the participants but, perhaps, also the staff. Given the insecurity of further funding in 2008, fewer participants may have been enticed to enroll. Additional factors could have affected the number of case management sessions attended, participation in the HGHH classes, enrollment, and retention rates. Programs could have initially targeted

Table 3 | Measurements of participation by enrollment year

	Enrollment year			
Measurement of participation	2006	2007	2008	*p* Value
Total participants	1123	985	802	
Mean number of case management visits during 1st year, all participants (*SD*)	6.98(3.29)[c]	7.12(3.38)[c]	6.03(3.29)[a,b]	<.0001
Participants with Year 1 assessment *n* (%)	818(72.8)	701(71.2)	508(63.3)	<.0001
Mean number of case management visits during 1st year among participants with Year 1 assessment (*SD*)	7.77(2.95)[b,c]	8.20(2.96)[a,c]	7.21(3.02)[a,b]	<.0001
Participants attending any HGHH classes during 1st year among participants with Year 1 assessment *n* (%)	613(75.0)	403(57.5)	268(53.5)	<.0001

p value for differences in means was determined by ANOVA; *p* value for differences in frequencies was determined by a chi-square test. *SD* standard deviation; *HGHH* Honoring the Gift of Heart Health.

[a]Significantly different from the mean of 2006 cohort at $\alpha = 0.017$ (based on Bonferroni correction for multiple comparisons).

[b]Significantly different from the mean of 2007 cohort at $\alpha = 0.017$ (based on Bonferroni correction for multiple comparisons).

[c]Significantly different from the mean of 2008 cohort at $\alpha = 0.017$ (based on Bonferroni correction for multiple comparisons).

participants who were highly motivated during the implementation of the program hoping to achieve initial results that were valuable to stakeholders, such as IHS, and their healthcare providers, tribes, and communities, in part to garner support and to maximize the probability of continued funding. On grantee annual recruitment and retention reports, staff members from SDPI-HH grantee sites indicated staffing issues, such as staff turnover and insufficient staffing levels, were endemic. With the increase in the number of participants annually requiring case management (participants were encouraged to remain in the program while funding lasted), in addition to recruiting and retention efforts, staffing issues could have led to a reduction in participation over time. Moreover, the primary reasons for lack of patient participation in the program, as reported by staff, were lack of time for the visits, transportation, and other competing commitments. Although the differences may be most apparent in the 2008 cohort, the trends across time are clear and suggest a complex interaction of system and funding issues in the face of higher participant needs concomitant with lower effectiveness. A model incorporating in-person case management with current electronic methods of communication and a more permanent and self-sustained form of funding may help maintain participation and adequate staffing.

All these findings have critical implications for future implementation policy decision making for large-scale translation of evidence-based interventions. For example, making case management reimbursable by health insurance could potentially increase staff stability, patient participation, and continued intervention effectiveness of a multi-year program. Furthermore, by demonstrating the importance of assessing changes over time in baseline characteristics, intervention effectiveness, and program participation, this study informs future revisions of the intervention to maximize continued effectiveness of an evidence-based intervention as it rolls out to real-world settings. Unlike randomized controlled trials where concerns about internal validity are paramount, external validity comes to the fore in translational interventions. Thus, as suggested by the results of the current study, a critical step for translational initiatives should be to develop data-driven approaches for intervention adaptation to address changes in patient, staff, and system characteristics over time to maintain similar levels of effectiveness and program participation. Such modifications must be thoughtful, of course, and attend to both internal and external validity concerns. Further, as always, such adaptations should also be designed in concert with the programs and patients.

Limitations

Important limitations deserve acknowledgment. Voluntary participation in the intervention may have resulted in a self-selection bias that limits the generalizability of these findings. Given that about 30% of the participants did not complete the first annual assessment, mixed models were used to provide unbiased estimates of the intervention effectiveness under the assumption of missing-at-random. This assumption cannot be easily assessed; thus, the lack of bias in our estimates may not be guaranteed, which could further limit the generalizability of our results [25]. Since the intervention activities in this initiative were based on previously demonstrated efficacy and current standards of care, an evaluation of the effectiveness of the intervention in real-world settings was deemed more appropriate than a design to document effects by comparison to a control group. Yet, without a control group, we cannot exclude the possibility that the improvements achieved by SDPI-HH participants were due to secular trends in usual care beyond the project instead of the SDPI-HH intervention. Lastly, provider and staffing issues over the 3 years may have contributed to the decline in participant recruitment, retention, and intervention outcomes.

However, the lack of quality data on provider and staff characteristics precludes us from rigorously evaluating this association which needs to be taken into consideration when designing future translational initiatives.

CONCLUSIONS

The results from this study demonstrate that the changes in baseline characteristics of SDPI-HH participants as time progressed, along with changes in staff composition, staff enthusiasm, and funding status, might have altered the effectiveness of the intervention. The changes in participant characteristics could be due to different participant availability for recruitment, with those at the start of the intervention being more motivated given their longer diabetes duration. Thus, it is critical to remain alert to the need for different strategies in subsequent years as well as being open to modifying the health behavioral models that underlie the intervention to accommodate potentially shifting characteristics of the target population. For instance, efforts to meaningfully target participant readiness to change should be considered for latter cohorts. Varying the method of delivering the intervention may also warrant further attention. Intensive case management has been reported to improve response to intervention, but may be impeded by high costs and the lack of availability of interested participants due to the level of commitment [26, 27]. An intervention that combines in-person case management and internet-based, peer-led programs or telephone technology to motivate, deliver, and monitor participants could reduce the burden on participants and staff, allowing more patients to benefit from the program. In addition, future studies investigating the impact of delivery-setting factors such as staff turnover, funding stability, and participants' competing priorities are critically needed to ensure continued provider and staff enthusiasm for the project and sustained fidelity of the intervention delivery. Lastly, investigations into how to modify a program to improve reach, motivation, and maintenance of a larger number of patients with diabetes are warranted to maximize the success of similar interventions for diabetes management among minority populations and to inform policy.

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Compliance with Ethical Standards

Primary Data: The authors have full control of all primary data, and they agree to allow the journal to review their data if requested.

Conflict of Interest: No authors have any competing interests or conflicts of interest.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The SDPI-HH protocol was approved by the institutional review board of the University of Colorado Anschutz Medical Center and the National IHS institutional review board. When required, grantees obtained approval from other entities, such as tribal review boards, which oversaw their program. This article does not contain any study with animals performed by any of the authors.

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