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Participant and Site Characteristics Related to Participant Retention in a Diabetes Prevention Translational Project

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Abstract

Using multi-level analysis, this study investigated participant and site characteristics associated with participant retention in a multi-site diabetes prevention translational project among American Indian and Alaska Native (AI/AN) people. We analyzed data from the Special Diabetes Program for Indians Diabetes Prevention Program (SDPI-DP), a lifestyle intervention to prevent diabetes implemented in 36 AI/AN grantee sites. A total of 2,553 participants were recruited and started the intervention between 01/01/2006 and 07/31/2008. They were offered the 16-session *Lifestyle Balance Curriculum* from the Diabetes Prevention Program (DPP) in the first 16-24 weeks of intervention. Generalized estimating equation models and proportional hazards models with robust standard error estimates were used to evaluate the relationships of participant and site characteristics with retention. As of 07/31/2009, about 50% of SDPI-DP participants were lost to follow-up. Those who were younger, male, with lower household income, no family support person, and more baseline chronic pain were at higher risk for both short-term and long-term retention failure (i.e., not completing all 16 DPP sessions and loss to follow-up, respectively). Sites with large user populations and younger staff had lower likelihood of retaining participants

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**Grant programs participating in the Special Diabetes Program for Indians Diabetes Prevention Demonstration Project: Confederated Tribes of the Chehalis Reservation, Cherokee Nation, Cheyenne River Sioux Tribe, the Chickasaw Nation, Coeur d'Alene Tribe, Colorado River Indian Tribes, Colville Confederated Tribes, Cow Creek Band of Umpqua Tribe, Fond du Lac Reservation, Gila River Health Care, Haskell Health Center, Ho-Chunk Nation, Indian Health Board of Minneapolis, Indian Health Center of Santa Clara Valley, Kenaitze Indian Tribe IRA, Lawton IHS Service Unit, Menominee Indian Tribe of Wisconsin, Mississippi Band of Choctaw Indians, Norton Sound Health Corporation, Pine Ridge IHS Service Unit, Pueblo of San Felipe, Quinault Indian Nation, Rapid City IHS Diabetes Program, Red Lake Comprehensive Health Services, Rocky Boy Health Board, Seneca Nation of Indians, Sonoma County Indian Health Project, South East Alaska Regional Health Consortium, Southcentral Foundation, Trenton Indian Service Area, Tuba City Regional Health Care Corporation, United American Indian Involvement, Inc., United Indian Health Services, Inc., Warm Springs Health & Wellness Center, Winnebago Tribe of Nebraska, Zuni Pueblo.

successfully. Other site characteristics related to higher risk for retention failure included staff rating of participant disinterest in SDPI-DP and barriers to participant transportation and child/elder care. Future translational initiatives need to pay attention to both participant- and site-level factors in order to maximize participant retention.

Keywords

Attrition; Dropout; American Indians and Alaska Natives; Lifestyle intervention; Community-based settings

Difficulties in participant recruitment and retention have been recognized as serious problems that potentially jeopardize the success of clinical trials (Probstfield and Frye 2011). Several key barriers to successful recruitment have been identified, including the lack of awareness for opportunities to participate in clinical trials, financial restraints of funding resources, and administrative burdens related to regulatory requirements (Probstfield and Frye 2011). Turning to retention, a meta-analysis found 12 basic themes for successful retention in clinical trials and observational studies (Robinson et al. 2007), such as community involvement, contact and scheduling methods, and financial incentives. No single optimal strategy was identified as high retention was usually associated with a combination of multiple strategies.

To address the problems of participant attrition, a wide range of studies have investigated factors related to retaining an individual in clinical trials and observational studies. Participant factors identified include age, gender, socioeconomic status, race, depression, anxiety, and alcohol involvement (Anderson et al. 2000; Bailey et al. 2004; Brown et al. 2000; Cassidy et al. 2001; Chang et al. 2009; Gappoo et al. 2009; Hessol et al. 2001; Noe et al. 2007; Shumaker et al. 2000; Warren-Findlow et al. 2003; Williams et al. 2008). With respect to staff characteristics, staff age, gender, training, professional education, as well as interpersonal skills have been associated with participant retention (Blanton et al. 2006; Brown et al. 2006; Manson et al. 2011). Site characteristics such as accessibility, location, and reminder system have also been linked to participant adherence (Edwards et al. 2009; Gappoo et al. 2009; Warren-Findlow et al. 2003; Williams et al. 2008). Although multiple studies discussed site and staff characteristics likely to be associated with retention qualitatively, with a few exceptions (Hessol et al. 2001; Hessol et al. 2009; McGuigan et al. 2003; O'Brien et al. 2012; Williams et al. 2008), few were based on large-scale multi-site data or rigorously investigated those associations using multilevel analysis. Furthermore, rarely did previous studies focus on retention issues among minority populations specifically (Martinez et al. 2012).

Recruitment and retention are equally critical to the success of efforts that seek to translate the findings of clinical trials in real-world settings. In order to maximize the reach of a proven intervention to all individuals who may need it, as many participants as possible should be recruited. Meanwhile, to sustain an effective intervention program, a high retention rate is critical to maximizing the benefits to participants as well as communities (Glasgow and Emmons 2007). Less rigorously controlled than clinical trials, translational efforts pose additional and special challenges for participant engagement. This is especially

true among minority populations, wherein participants typically are more difficult and costly to recruit and retain (Garfield et al. 2003; Probstfield and Frye 2011). Moreover, attempts at translation typically command fewer resources to intensively follow and track participants, thus further jeopardizing retention success. To date, however, the strategies and potential predictors for retention success in translational initiatives remain underexplored (Davis et al. 2009; Rosal et al. 2010).

Our group previously investigated factors related to short-term retention success in a translational project to reduce cardiovascular disease risk among American Indian and Alaska Natives (AI/ANs) with diabetes – the Special Diabetes Program for Indians (SDPI) Healthy Heart (HH) demonstration project (Manson et al. 2011). We found participant age, baseline BMI, physical activity level, as well as the average age, gender composition, and education level of site staff were significantly associated with retention success. Yet, only one year of data were available in that study, which did not allow us to examine potential predictors for long-term retention. In the current study, we focus on the other arm of the SDPI demonstration projects, known as the SDPI diabetes prevention (SDPI-DP) program (Jiang et al. 2013). Although SDPI-DP and SDPI-HH are both translational projects aiming to prevent chronic diseases, one of the differences between the two projects is that the intervention of SDPI-DP has two phases: an initial intensive phase followed by a maintenance phase. This feature makes it particularly important to investigate short-term and long-term retention separately. The SDPI-DP was carried out among AI/ANs with pre-diabetes recruited from 36 diverse grantee sites who were followed up for a maximum of 3.6 years, offering data to assess the relationship of participant and site characteristics with both short-term and long-term retention. Furthermore, additional site characteristics hypothesized to affect retention success became available in this study. We hypothesized that older participants with higher household income, lower baseline pain, and more family support are more likely to be retained in the study. In addition, grantee sites with more matured and better educated staff have higher chance for retention success. Also, sites with more staff reporting their participants lack interest in SDPI-DP have lower short-term and long-term retention rates. Finally, sites with higher staff rating on the difficulties that their participants experienced in transportation and/or care-taking responsibilities are at higher risk for participant drop-out, especially long term.

METHODS

SDPI-DP

The SDPI-DP Program is a congressionally mandated demonstration project designed to reduce diabetes incidence among AI/ANs with pre-diabetes through implementation of a lifestyle intervention. In 2004, 36 health care programs received funding to participate in the SDPI-DP. Grantees represented a diverse mix of programs, serving 80 tribes in 18 states and 11 Indian Health Service (IHS) administrative areas. These programs included 6 IHS hospitals/clinics and 30 tribal or IHS-contracted health care programs administered by tribes. The SDPI-DP protocol was approved by the institutional review board (IRB) of the University of Colorado Denver and the National IHS IRB. When required, grantees obtained approval from other entities charged with overseeing research in their programs (e.g., tribal

review boards). All participants provided written informed consent and Health Insurance Portability and Accountability Act authorization.

The participating programs were required to implement the 16-session *Lifestyle Balance Curriculum* drawn from the Diabetes Prevention Program (DPP) (Knowler et al. 2002) and to participate in the evaluation of the effectiveness of their prevention activities. As in the DPP lifestyle intervention arm, the primary goal of the intervention was to achieve and maintain a weight reduction of at least 7% of initial body weight through a healthy diet and increased physical activity. In the initial intensive phase of the intervention, the curriculum was delivered in group settings within 16-24 weeks after baseline assessment and typically was taught by the program dietitian and/or health educator. It was supplemented by monthly one-to-one individual lifestyle coaching sessions to individualize goals and plans and to identify and solve barriers to participation. In the maintenance phase of the intervention, monthly one-to-one lifestyle coaching sessions continued to support the participants in sustaining the lifestyle changes they made after attending the curriculum, and to evaluate the long-term effectiveness of this program.

Participants

Participants were recruited locally by each grant program. Eligibility criteria were being AI/AN (based on their eligibility to receive IHS services), being at least 18 years of age, and having either impaired fasting glucose (i.e., a fasting blood glucose (FBG) level of 100 to 125 mg/dl and an oral glucose-tolerance test (OGTT) result <200 mg/dL) and/or impaired glucose tolerance (i.e., an OGTT result of 140 to 199 mg/dl 2 hours after a 75-g oral glucose load and a FBG level <126 mg/dL). Four exclusion criteria were used: 1) a previous diagnosis of diabetes; 2) pregnancy; 3) End Stage Renal Disease on dialysis; and 4) active alcohol or substance abuse, current diagnosis of cancer, or any other condition that would affect successful participation based on provider judgment. Enrollment began on 01/01/2006 and is ongoing. The present study included baseline and retention data from 2,553 participants who completed the baseline assessment and started the intervention by 07/31/2008. The retention data were available for those participants between their baseline assessments and 07/31/2009.

Measures

At baseline, within a month of completing the last DPP class (usually 4-6 months after baseline), and annually after baseline, participants underwent a comprehensive clinical assessment to evaluate diabetes risk and incidence. At the same time points, each participant completed a questionnaire encompassing sociodemographics, health-related behavior, and a range of psychosocial factors. In this study, short-term retention success for a participant was defined as completing all 16 DPP curriculum sessions. Long-term retention was measured by time to loss to follow-up (LTFU), which was the time between the date a participant started intervention and the date a participant became inactive in the project as reported by the site staff for any reason other than diabetes conversion, death, or pregnancy. Participants who converted to diabetes, died, or became pregnant by 07/31/2009 and those who were still active after 07/31/2009 were treated as censored observations. We examined

the association between retention and the following participant- and site-level characteristics.

Participant Characteristics

Sociodemographics: Participants answered questions related to their sociodemographic characteristics, including age, gender, educational attainment, employment status, marital status, and annual household income.

Clinical Indicators: Baseline physical examination included measurements of height, weight, and sitting systolic and diastolic blood pressure. Body Mass Index was calculated from height and weight (kg/m^2). Blood was drawn after a 9-12-hour fast to measure blood glucose level, triglycerides, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol. In addition, self-reported number of comorbid conditions was assessed using the Self-Administered Comorbidity Questionnaire (Sangha et al. 2003).

Psychosocial factors: Participants were queried about a wide range of psychosocial factors that may be related to retention, including distress, anxiety, pain, family support, smoking, physical activity, diet, and stages of change for exercise, diet, and weight loss. Bivariate analyses indicated the following variables were significantly or marginally related to short-term and/or long-term retention:

1. **Distress.** The Kessler Distress Scale (Furukawa et al. 2003) is a general measure of psychological distress often used to screen for serious emotional problems. Previously, it has been shown to be related to retention (Chang et al. 2009; Katzer et al. 2008; Yass-Reed et al. 1993). SDPI-DP used the 6-item version (K6; $\alpha = 0.88$; range 1-5).
2. **Pain.** A visual analog pain scale (range 1-10) was used to assess each participant's perception of general pain (Carlsson 1983; Jerome and Gross 1991).
3. **Smoking status.** History and current status of cigarette smoking were collected using items from the American Indian Service Utilization, Psychiatric Epidemiology, Risk and Protective Factors Project (Nez Henderson et al. 2005).
4. **Family support.** The availability of a family support person was determined by having a family member complete a brief family questionnaire at baseline.

Site Characteristics—Site-specific factors included type of grant program organization (IHS hospital or clinic or tribal health care program), the user population of the health facility of each grantee site (small [less than 5,000 users], medium [5,000-9,999], and large [10,000]), and the number of participants accrued at each site (< 50 vs. >50). The characteristics of staff members at each grantee site were obtained from a Provider Annual Questionnaire (PAQ) completed by grantee staff members. In this study, we examined the relationship between retention and average age of staff members (<40 vs. 40 years), proportion of female staff (< 70% vs. >70%), and proportion of staff members who completed graduate/professional school (<50% vs. 50%).

In addition, on the PAQs, site staff members were asked to answer a series of questions, developed by study staff and grantees, regarding their opinions about SDPI-DP, their experience in retaining participants, and their experience in coordinating with other staff in their organizations. The answers to each of these questions have a range of 1-5, where 1 equals strongly disagree and 5 equals strongly agree. Based on the results of exploratory factor analyses, answers to these questions were summarized by 8 different scale variables including 1) program teamwork and leadership (8 items; α [Cronbach's alpha]=0.86); 2) staff belief and knowledge about the program (6 items, $\alpha=0.74$); 3) lack of time that program staff was able to dedicate to SDPI-DP (5 items, $\alpha=0.72$); 4) staff rating of participants' lack of interest in SDPI-DP (4 items, $\alpha=0.81$); 5) staff rating on the appropriateness of program content and focus (4 items, $\alpha=0.78$); 6) staff rating on the lack of transportation or child/elder care among their participants (2 items, $\alpha=0.85$); 7) lack of support for SDPI-DP from their organization (3 items, $\alpha=0.84$); 8) staff turnover (2 items, $\alpha=0.82$).

The PAQs were completed by site staff at 3 time points: December 2006, 2007, and 2008. In the current study, we used the averages of those 3 time points for each of the measurements collected from the PAQs as potential factors affecting short-term and long-term retention. Two grantee sites had very low response rates for the PAQs (< 2 per year), hence those two sites were excluded from all the analysis that used data from the PAQs.

Statistical Analysis

Short-term retention (completed all 16 DPP classes or not) was used as a dichotomous variable in all data analyses, while long-term retention (time to loss to follow-up) was analyzed as a time to event variable. Bivariate associations between short-term retention and participant-level factors were examined using logistic regressions, with one participant factor included in each of the bivariate models. Bivariate associations between long-term retention and participant-level variables were evaluated using Cox proportional hazards regression models. In multi-site intervention studies, an intraclass correlation (ICC) as small as 0.02 could substantially change the standard error estimates for the association between upper level factors and outcomes (Donner and Klar 2000). Therefore, to account for within-site clustering, generalized estimation equation (GEE) models with a logit link and an exchangeable correlation matrix were used to examine the bivariate associations between short-term retention and site-level factors. Similarly, Cox regression models with robust standard error estimators were used to assess the bivariate relationship between long-term retention and site-level characteristics.

Factors with p -values $<.25$ in the bivariate analyses were entered into multivariate models in a block-wise manner. More specifically, all the participant-level factors with p -values $<.25$ in the bivariate analyses were entered into the multivariate model first, which was then reduced by gradually deleting variables with p -values $>.2$. We then entered all site-level factors with p -values $<.25$ into the previous model, and reduced that model by gradually excluding variables with p -values $>.2$. GEE models and Cox models with robust standard error estimates were utilized for the final multivariate regression models. All data analyses were conducted using SAS 9.2 software (SAS Institute, 2008).

Missing data were uncommon for most of the variables included in this analysis (5%) except income and marital status (20% and 16%, respectively). Still, in the multiple regression models without imputation, about one third of the observations were excluded due to missing data on one or more variables. To avoid potential bias caused by excluding incomplete cases and to maximize the power of the analysis, a multiple imputation method was used to impute missing data before the final multivariable models were fit. The multiple imputations were performed using IVEware developed by the University of Michigan Survey Methodology Center (Raghunathan et al. 2009). Twenty imputed datasets were generated this way and the final GEE and Cox models were fit in each of the 20 datasets. The results were then combined using the SAS MIANALYZE procedure to obtain the proper estimate for the standard error of each parameter of interest.

RESULTS

As of 07/31/2008, 2,553 participants had enrolled in SDPI-DP and started the intervention. They were followed for an average of 1.6 years (range: 1 day to 3.6 years) by the end date of the data collection reported here (07/31/2009). Sixty-eight percent (1,740) of these participants completed all 16 DPP curriculum sessions, and fifty percent (1,288) of participants were LTFU by July 31, 2009. The average length of follow-up was 0.9 years for those who were LTFU and 2.4 years for active participants. Among those who were LTFU, 11% (138) were excluded from further participation because of diabetes conversion, 3 were excluded due to death and 36 due to pregnancy. As shown in Figure 1, among those who became inactive before 20 weeks (approximately the end of the DPP curriculum), the most prevalent reason for LTFU was scheduling difficulties or family problems (50%), and the next most common reason for LTFU was unable to contact the participant (19%). Among those who became inactive after 20 weeks, both scheduling difficulties and unable to contact were the most common reasons for LTFU, with about 20% of the participants dropped out for each of those reasons.

Table 1 describes the baseline characteristics of SDPI-DP participants enrolled by 07/31/2008. The majority of participants were female (74.5%), employed (74.0%), and married or living in a “marriage-like” relationship (58.8%). The average age of the participants was 46.8 years old with a standard deviation of 12.4. Most participants attended some years of college (45.4%) or graduated from college (19.4%). Table 1 also shows that the participants who were older, female, retired, married or in a “marriage-like” relationship, with higher education and income had lower attrition rates than the others at both the end of the DPP curriculum and the end of this study.

Among the 36 SDPI-DP grantee sites, on average 8 staff members responded to the Provider Annual Questionnaire each year. As mentioned above, two sites had very low response rates and their data were excluded from subsequent analyses. Attrition rates by categorical site characteristics are illustrated in Table 2. Sites with medium-sized user population, older staff (average age 40 years) and less female staff (70%) had relatively higher retention rates at both the end of the DPP curriculum and the end of this study.

Table 3 presents the bivariate associations between participant characteristics and retention. Older, female, and retired participants were significantly more likely to complete all 16 DPP classes and had lower risk for LTFU. Those who had less education and lower income were at significantly higher risk for both short-term and long-term retention failure. No clinical indicators were significantly associated with retention. Higher baseline distress and pain level were associated with an increased risk for failure to complete 16 classes and LTFU. Current smokers had significantly higher likelihood of not completing 16 classes than nonsmokers. The presence of a family support person was significantly associated with lower risk for both short-term and long-term retention failure.

The bivariate associations between site-specific characteristics and retention are revealed in Table 4. Medium-sized sites in terms of user population (5,000 - 10,000) had significantly lower risk for short-term and long-term retention failure than large-sized sites (>10,000 patients). The sites with younger staff members (average age <40 years) exhibited lower likelihood of retaining participants than did sites with older staff. A higher proportion of female staff members (>70%) was significantly associated with short-term attrition, but not long-term attrition. In terms of staff ratings of program and retention experience, GEE models and robust Cox regressions indicated only two factors were significantly associated with retention: staff rating of participant disinterest in SDPI-DP and barriers to participant transportation or child/elder care. Sites reporting lower participant interest and more problems in transportation or care-taking responsibilities had significantly or marginally higher risk for both short-term and long-term retention failure than the other sites.

The final multivariate GEE model for not completing all 16 DPP classes and the Cox regression model for LTFU are presented in Table 5. They indicate that older and female participants had significantly decreased risk for both short-term and long-term attrition. In addition, participants with less household income, no family support person, and more chronic pain had higher risk for retention failure. With respect to site characteristics, medium-sized sites in terms of user population had significantly lower rates of not completing all 16 classes than large-sized sites (OR=0.64, $p=.01$). Younger average age of staff members (<40 years) and higher staff rating on participant disinterest were marginally associated with higher likelihood for short-term retention failure (OR=1.44, $p=.09$; OR=2.74, $p=.10$, respectively). Furthermore, younger staff members (average age <40 years) and higher staff rating of participants' lack of transportation or child/elder care were significantly correlated with higher risk for LTFU (HR=1.52, $p=.04$; HR=1.85, $p=.01$, respectively).

DISCUSSION

One of the first large-scale, multi-site diabetes prevention translational initiatives implemented in a minority population, SDPI-DP was successful at recruiting a substantial number of participants. However, retaining them in the program, especially long-term, has proven to be challenging. By 07/31/2009, when the participants were followed for an average of 1.6 years, 44% of them had become voluntarily inactive, in addition to those who discontinued due to diabetes conversion, death, or pregnancy. Such a LTFU rate is not unusual for translational efforts of this nature, especially for projects of this magnitude.

Several other diabetes prevention translational projects have reported similar retention rates (Ackermann et al. 2008; Saaristo et al. 2010; Seidel et al. 2008; Vanderwood et al. 2010), but few of them reported reasons for participant attrition. For SDPI-DP participants, busy and stressful lives made it hard for some to attend all 16 sessions or meet monthly with their lifestyle coaches. Indeed, the most common reason for withdrawal was scheduling difficulties. The greater likelihood of older and retired participants staying in the program may reflect fewer challenges related to scheduling among this group.

Our results regarding the relationships between participant characteristics and retention among these AI/AN participants are generally consistent with the existing preventive intervention literature. Specifically, we found that male gender, younger age, lower household income, absence of a family support person, and more baseline chronic pain were associated with higher risk of both short-term and long-term retention failure. Excluding family support and chronic pain, these other factors have been consistently documented as related to higher risk for LTFU in previous studies (Anderson et al. 2000; Bailey et al. 2004; D. R. Brown et al. 2000; Chang et al. 2009; Gappoo et al. 2009; O'Brien et al. 2012; Warren-Findlow et al. 2003). The role of family support in diabetes management has been clearly identified (Rosland et al. 2008; Schafer et al. 1986). Here we found that the presence of a family support person also was strongly associated with lower risk of retention failure, suggesting retention in future lifestyle intervention projects may be improved by active involvement of and support from a participant's family. On the other hand, the relationship between pain and retention highlights the importance of pain management for successful retention in future translational efforts, especially with respect to relatively older participants.

Turning to site-level factors, we identified multiple site and staff characteristics that are related to retention. First, sites with large user populations, representing relatively large communities, had less success in both short-term and long-term retention. This may reflect difficulties in tracking and maintaining contact with participants among sites with a relatively large pool of potential participants. Consistent with previous reports, sites with relatively older staff were more successful at both short-term and long-term retention, stressing the importance of hiring and retaining more mature and experienced staff for sustainability. Higher staff rating of participant disinterest in SDPI-DP was associated with more retention failure, signaling the importance of engaging and sustaining participant interest for retention purpose. As revealed in a recent study of participant attrition using mixed methods, staff members in low-attrition sites reported being adaptive to the participants' needs and specific concerns in order to keep engaging them (O'Brien et al. 2012). The higher staff rating of participant disinterest at the sites with low retention rates in this study may imply the lack of effective and flexible ways of interacting with participants among the staff at those sites. Future studies that investigate the retention strategies used by different grantee sites to stimulate and keep participants' interests in the program are needed to further elucidate the mechanism for this observed relationship. Finally, staff rating of lack of transportation and care-taking responsibilities significantly correlated with long-term retention, but not short-term retention. This may speak to the relative ease of finding temporary solutions to transportation problems or child/elder care responsibilities, but greater challenge of addressing long-term needs.

One of the strengths of this study is the use of multi-level analysis to examine the relationship between site-level factors and time to LTFU. In this study, the estimated ICC for short-term and long-term retention was 0.09 and 0.06, respectively. Taking these ICCs into consideration leads to dramatic changes in the p -values for most site characteristics, but little change in the p -values for participant-level factors (data not shown). This observation confirms the importance of using proper multi-level analytical methods when working on data with multi-level data structures, especially for assessing the relationships between upper-level covariates and outcomes. To date, however, although multi-level linear and generalized linear models are quite commonly used, multi-level survival analysis has received less attention and has been employed less frequently when dealing with clustered failure-time data.

Several limitations qualify these findings. First, the Provider Annual Questionnaires were collected only at the end of 2006, 2007, and 2008. Further, although requested to do so, not all site staff members responded to this questionnaire each year. Indeed, provider data from two sites were excluded due to low response rates. Hence, we may not have captured the full picture of provider characteristics during the study period. Second, we did not directly measure a number of site characteristics that may be related to retention. For example, transportation problems were only measured by staff ratings of participants' lack of transportation when describing their retention experience. We did not directly assess a site's efforts to provide transportation to participants. Finally, SDPI-DP has 36 grantee sites, which may have limited statistical power in identifying significant relationships between site characteristics and retention. Simulation studies have shown the estimations for fixed effects in multi-level logistic regression models might be biased for 30 clusters with small sample size in each cluster (Moineddin et al. 2007). However, since the average cluster size was approximately 70 in this study, the bias should not be substantial.

In summary, as one of the largest projects to translate a lifestyle intervention into the real-world settings of an underserved population, the SDPI-DP faced many challenges in sustaining the program in the AI/AN communities. This study has identified a number of baseline participant- and site-level factors that were associated with participant retention. Most of the site-level factors are amenable to change, and doing so in future efforts may lead to better retention outcomes. The baseline participant characteristics (such as younger age), while not modifiable, provide opportunities for the development of targeted retention strategies for participants with high attrition risk upon enrollment in order to maximize retention.

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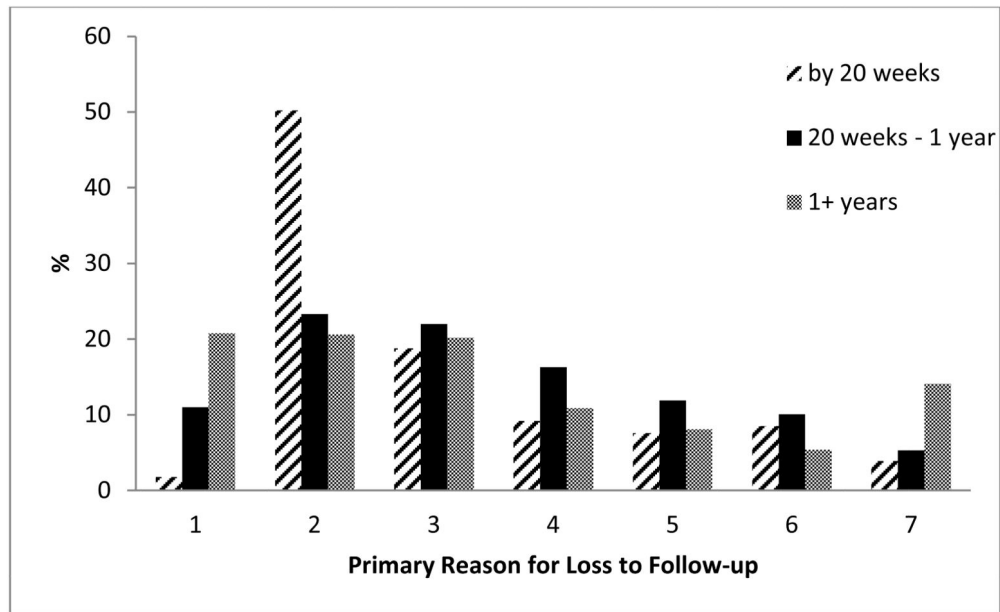
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Reasons for loss to follow-up:

| | |
|---|--|
| 1 | Converted to diabetes |
| 2 | Scheduling difficulties or family problems |
| 3 | Unable to contact |
| 4 | Moved away |
| 5 | Did not like program |
| 6 | Health problems |
| 7 | Other |

Figure 1. Reasons for Loss to Follow-up among SDPI-DP Participants

Table 1
SDPI-DP attrition rates by baseline categorical participant characteristics

| Characteristics | # of participants (%) | % not completing 16 DPP classes | % Lost to Follow-up |
|----------------------------|-----------------------|---------------------------------|---------------------|
| Total | 2553 (100.0) | 31.8 | 50.4 |
| Age | | | |
| 18 to < 40 years | 731 (28.6) | 37.1 | 59.9 |
| 40 to < 50 years | 774 (30.3) | 31.0 | 48.8 |
| 50 to < 60 years | 645 (25.3) | 30.7 | 47.5 |
| >= 60 years | 403 (15.8) | 25.8 | 40.9 |
| Gender | | | |
| Female | 1901 (74.5) | 30.4 | 49.6 |
| Male | 652 (25.5) | 36.2 | 52.9 |
| Education Status | | | |
| < high school | 318 (14.1) | 35.2 | 51.3 |
| high school graduate | 477 (21.1) | 29.6 | 48.6 |
| some college | 1024 (45.4) | 28.8 | 49.8 |
| >= college graduate | 438 (19.4) | 24.0 | 44.5 |
| Employment Status | | | |
| Employed | 1665 (74.0) | 28.2 | 48.3 |
| Retired | 168 (7.5) | 20.8 | 38.1 |
| Unemployed/student | 416 (18.5) | 36.3 | 56.5 |
| Marital Status | | | |
| Married/live together | 1189 (58.8) | 27.8 | 45.7 |
| Separated/divorced/widowed | 510 (25.2) | 30.0 | 53.7 |
| Never married | 323 (16.0) | 32.8 | 56.7 |
| Annual Household Income | | | |
| < 15k | 371 (19.4) | 38.0 | 57.1 |
| 15 to < 30k | 411 (21.5) | 30.4 | 51.5 |
| 30 to < 50k | 569 (29.8) | 25.7 | 46.9 |
| >= 50k | 558 (29.2) | 23.1 | 44.4 |

Table 2
SDPI-DP attrition rates by categorical site characteristics

| Characteristics | # of sites | # of participants | % not completing 16 DPP classes | % Lost to Follow-up |
|---|------------|-------------------|---------------------------------|---------------------|
| Total | 36 | 2553 | 31.84 | 50.43 |
| Organization | | N (%) | | |
| IHS | 6 | 458 (19.1) | 28.4 | 51.9 |
| Tribal | 28 | 1943 (80.9) | 31.2 | 48.6 |
| User population size | | | | |
| Small (< 5,000) | 10 | 505 (21.0) | 38.8 | 47.2 |
| Medium (5, 000 – 9,9999) | 11 | 749 (31.2) | 19.5 | 40.2 |
| Large (>=10,000+) | 13 | 1147 (47.8) | 34.4 | 56.1 |
| Total accrual number by 07/31/08 | | | | |
| 50 participants | 11 | 404 (16.8) | 25.0 | 48.0 |
| > 50 participants | 23 | 1997 (83.2) | 31.8 | 49.5 |
| Average age of staff members | | | | |
| < 40 years | 11 | 835 (34.8) | 38.4 | 61.1 |
| 40 years | 23 | 1566 (65.2) | 26.5 | 42.9 |
| Proportion of female staff | | | | |
| 70% | 9 | 562 (23.4) | 22.6 | 43.8 |
| > 70% | 25 | 1839 (76.6) | 33.1 | 50.9 |
| Proportion of staff completing graduate/professional school | | | | |
| < 50% | 18 | 1257 (52.4) | 33.7 | 49.7 |
| 50% | 16 | 1144 (47.6) | 27.3 | 48.8 |

Table 3
Bivariate association between participant characteristics and retention

| Participant Characteristics | Failure to Complete 16 DPP Classes | | Time to Loss to Follow-up | | |
|-----------------------------------|------------------------------------|-----------------|---------------------------|------------------------------|-------------------------------------|
| | GEE Models | | Cox Regression Models | | |
| | OR | <i>p</i> -value | HR | <i>p</i> -value ^a | Robust <i>p</i> -value ^b |
| Sociodemographics | | | | | |
| Age (10 years) | 0.86 | <.001 | 0.86 | <.001 | <.001 |
| Female | 0.75 | .004 | 0.82 | .002 | <.001 |
| Education Status | | | | | |
| < high school | 1.00 | NA | 1.00 | NA | NA |
| high school graduate | 0.77 | .04 | 0.81 | .05 | .06 |
| some college | 0.69 | .005 | 0.84 | .06 | .09 |
| >= college graduate | 0.57 | <.001 | 0.69 | .001 | .002 |
| Employment Status | | | | | |
| Employed | 1.00 | NA | 1.00 | NA | NA |
| Retired | 0.67 | .05 | 0.71 | .01 | .03 |
| Unemployed/student | 1.38 | .07 | 1.39 | <.001 | .004 |
| Marital Status | | | | | |
| Married/live together | 1.00 | NA | 1.00 | NA | NA |
| Never married | 1.06 | .65 | 1.46 | <.001 | <.001 |
| Separated/divorced/widowed | 1.16 | .37 | 1.21 | .02 | .011 |
| Annual Household Income | | | | | |
| < 15k | 1.77 | .001 | 1.53 | <.001 | <.001 |
| 15 to < 30k | 1.35 | .003 | 1.23 | .04 | .05 |
| 30 to < 50k | 1.12 | .39 | 1.05 | .58 | .64 |
| >= 50k | 1.00 | NA | 1.00 | NA | NA |
| Clinical Indicators | | | | | |
| Body Mass Index (10 units) | 0.97 | .47 | 1.05 | .23 | .23 |
| # of comorbid conditions | 0.98 | .15 | 1.00 | .69 | .80 |
| Psychosocial Factors | | | | | |
| Kessler Distress Scale | 1.11 | .06 | 1.12 | .01 | .009 |
| Pain Visual Assessment | 1.04 | .02 | 1.04 | .007 | .03 |
| Current smoker | 1.27 | .006 | 0.99 | .18 | .80 |
| Presence of family support person | 0.60 | <.001 | 0.70 | <.001 | <.001 |

^a *p*-values of the regression parameters based on model-based standard errors.

^b *p*-values of the regression parameters based on robust (sandwich) standard errors.

Table 4
Bivariate association between site characteristics and retention

| Site Characteristics | Failure to Complete 16 DPP Classes | | Time to Loss to Follow-up | | |
|---|---------------------------------------|-----------------|---------------------------|------------------------------|--|
| | GEE Models | | Cox Regression Models | | |
| | OR | <i>p</i> -value | HR | <i>p</i> -value ^a | Robust <i>p</i> -value ^b |
| Organization type | | | | | |
| IHS | 1.00 | NA | 1.00 | NA | NA |
| Tribal | 1.16 | .50 | 0.85 | .03 | .33 |
| User population size | | | | | |
| Small (< 5,000) | 1.11 | .77 | 0.76 | <.0001 | .15 |
| Medium (5,000 – 10,000) | 0.57 | .03 | 0.58 | <.0001 | .02 |
| Large (10,000) | 1.00 | NA | 1.00 | NA | NA |
| Total accrual number by 07/31/08 | | | | | |
| <= 50 participants | 0.80 | .42 | 0.76 | .0009 | .15 |
| > 50 participants | 1.00 | NA | 1.00 | NA | NA |
| Average age of staff members | | | | | |
| < 40 years | 1.60 | .07 | 1.81 | <.0001 | .005 |
| >= 40 years | 1.00 | NA | 1.00 | NA | NA |
| Proportion of female staff | | | | | |
| <=70% | 0.54 | .01 | 0.81 | .008 | .28 |
| > 70% | 1.00 | NA | 1.00 | NA | NA |
| Proportion of staff completing graduate/professional school | | | | | |
| < 50% | 1.41 | .20 | 0.99 | .97 | .99 |
| >= 50% | 1.00 | NA | 1.00 | NA | NA |
| Staff ratings about SDPI-DP: | | | | | |
| Teamwork and leadership | 0.88 | .77 | 0.68 | .003 | .32 |
| Belief and knowledge | 1.24 | .81 | 1.86 | .001 | .51 |
| Lack of time for SDPI-DP | 1.29 | .56 | 1.49 | <.001 | .21 |
| Staff's experience in retaining participants | | | | | |
| Participants lack interest | 4.45 | .007 | 2.91 | <.001 | .02 |
| Content and focus not appropriate | 1.03 | .96 | 1.45 | .009 | .39 |
| Participants lacked transportation or child/elder care | 1.84 | .07 | 2.28 | <.001 | <.001 |
| Staff experience coordinating with other staff in their organization | | | | | |
| Lack of support for the program | 1.04 | .90 | 1.21 | .05 | .51 |
| Staff turnover | 1.03 | .92 | 1.32 | <.001 | .27 |

^a *p*-values of the regression parameters based on model-based standard errors.

^b *p*-values of the regression parameters based on robust (sandwich) standard errors.

Table 5
Final multivariate regression models for short-term and long-term retention

| Characteristics | GEE model for Failure to Complete 16 DPP Classes | | | | Cox model for Time to Loss to Follow-up | | | |
|--|---|--------|------|------------------------------|--|--------|------|--|
| | OR ^a | 95% CI | | <i>p</i> -value ^b | HR ^c | 95% CI | | Robust <i>p</i> -value ^d |
| Participant characteristics | | | | | | | | |
| Age (10 years) | 0.86 | 0.81 | 0.92 | <.001 | 0.84 | 0.78 | 0.89 | <.001 |
| Female | 0.70 | 0.55 | 0.87 | .002 | 0.79 | 0.71 | 0.89 | <.001 |
| Annual Household Income | | | | | | | | |
| < 15k | 2.02 | 1.43 | 2.84 | <.001 | 1.36 | 1.11 | 1.66 | .003 |
| 15 to < 30k | 1.52 | 1.18 | 1.95 | .001 | 1.20 | 0.98 | 1.48 | .09 |
| 30 to < 50k | 1.19 | 0.89 | 1.59 | .23 | 1.02 | 0.83 | 1.24 | .88 |
| 50k | 1.00 | NA | NA | NA | 1.00 | NA | NA | NA |
| Comorbidity Index | 0.96 | 0.92 | 1.00 | .06 | | | | |
| Presence of family support person | 0.62 | 0.50 | 0.78 | <.001 | 0.70 | 0.57 | 0.87 | .001 |
| Pain Visual Assessment | 1.06 | 1.01 | 1.11 | .03 | 1.04 | 1.00 | 1.08 | .03 |
| Site characteristics | | | | | | | | |
| User population size | | | | | | | | |
| Small (< 5,000) | 0.97 | 0.45 | 2.13 | .95 | | | | |
| Medium (5,000 – 10,000) | 0.64 | 0.46 | 0.90 | .01 | | | | |
| Large (10,000+) | 1.00 | NA | NA | NA | | | | |
| Average age of staff members | | | | | | | | |
| < 40 years | 1.44 | 0.94 | 2.18 | .09 | 1.52 | 1.02 | 2.27 | .04 |
| 40 years | 1.00 | NA | NA | NA | 1.00 | NA | NA | NA |
| Participants lack interest | 2.74 | 0.84 | 8.95 | .10 | | | | |
| Participants lack transportation or child/elder care | | | | | 1.85 | 1.15 | 2.96 | .01 |

^aOdds ratios (OR) of failure to complete 16 DPP classes from the final generalized estimating equation (GEE) model with both participant and site factors included in the model.

^bTwo-sided *p*-values from Wald tests of regression parameters in the final generalized estimating equation model based on empirical (robust) covariance estimator.

^cHazard ratios (HR) of time to loss to follow-up from the final Cox proportional hazards regression models with both participant and site factors included in the model.

^dTwo-sided *p*-values from Wald tests of regression parameters in the final Cox proportional hazards models based on robust (sandwich) standard errors.