# Spanish Diabetes Self-Management With and Without Automated Telephone Reinforcement

## Two randomized trials

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**OBJECTIVE** — To determine *1*) whether participants in the Spanish Diabetes Self-Management Program (SDSMP), when compared at 6 months to randomized control subjects, would demonstrate improvements in health status, health behaviors, and self-efficacy; and *2*) whether SDSMP participants receiving monthly automated telephone reinforcement would maintain improvements at 18 months better than those not receiving reinforcement.

**RESEARCH DESIGN AND METHODS** — A total of 567 Spanish-speaking adults with type 2 diabetes were randomized to a usual-care control group or 6-week community-based, peer-led SDSMP. SDSMP participants were re-randomized to receive 15 months of automated telephone messages or no reinforcement. A1C was measured at baseline and 6 and 18 months. All other data were collected by self-administered questionnaires.

**RESULTS** — At 6 months SDSMP participants compared with control subjects demonstrated improvements in A1C (−0.4%), health distress, symptoms of hypo- and hyperglycemia, and self-efficacy ($P < 0.05$). At 18 months all improvements persisted ($P < 0.05$). SDSMP participants also demonstrated improvements in self-rated health and communication with physicians, had fewer emergency room visits (−0.18 visits in 6 months, $P < 0.05$), and trended toward fewer visits to physicians. At 18 months the only difference between reinforced and nonreinforced participants was increased glucose monitoring for the reinforcement group.

**CONCLUSIONS** — The SDSMP demonstrated effectiveness in lowering A1C and improving health status. Reinforcement did not add to its effectiveness. Given the high needs of the Spanish-speaking population, the SDSMP deserves consideration for implementation.

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Type 2 diabetes affects 9.5% of the Latino population over 20 years of age, and its prevalence is increasing (1). While the need for self-management support is well documented, there are few long-term studies indicating its effectiveness. We report on a randomized, controlled trial of the community-based, peer-led Spanish Diabetes Self-Management Program (SDSMP). As potential reinforcement, half of SDSMP participants were re-randomized to receive monthly automated telephone messages.

We hypothesized that *1*) participants receiving the SDSMP, compared with randomized control subjects at 6 months, would demonstrate improvements in health-status, self-management behaviors, and self-efficacy; and 2) the benefits of the SDSMP would be better maintained after 18 months by participants receiving monthly automated telephone reinforcement than by those with no reinforcement.

The prevalence of diabetes is nearly three times greater among Latinos than non-Latinos (2) and is also metabolically more severe (3–5). The high rate of morbidity is likely to continue (6).

In reviewing the self-management literature for Spanish speakers, four articles reported on the feasibility of a single community-based education and support program (7–10). Findings appear promising with significant 12-month improvements in A1C. This intervention may not be generalizable because it depends on Spanish-speaking health professionals, who are often not available to those patients (11). Two other studies took place in Argentina and Cuba (12,13), and neither reported positive outcomes for health status or health care utilization. Gerber et al. (14) used waiting room kiosks to offer diabetes education to a diverse population. At 1 year, no difference was found in A1C. Rosal et al. (15) reported on a randomized diabetes self-management trial using a cognitive behavioral framework, and at 6 months participants demonstrated a greater decrease in A1C than control subjects. Piette et al. (16,17) found that low-income patients, including Spanish speakers, who received automated telephone calls with nurse follow-up, when compared with control subjects not receiving calls, reported less depression, greater self-efficacy, and fewer days in bed because of illness. The reinforcement intervention in the present study was based on this finding.

## RESEARCH DESIGN AND METHODS

— This article reports on two studies *1*) a randomized 6-month trial of the SDSMP, with an 18-month longitudinal follow-up, and *2*) an 18-month randomized comparison of automated telephone reinforcement of the SDSMP versus the nonreinforced SDSMP.

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**Abbreviations:** SDSMP, Spanish Diabetes Self-Management Program.

### SDSMP

The SDSMP was developed based on needs assessments conducted with four groups of Latinos with diabetes and three groups of diabetes educators. It was then reviewed by diabetes nurse educators, nutritionists, and a diabetologist and modified to be "translatable" for real-world practice. The program protocol and all program material were originally written in Spanish. In a pilot study using a pretest/post-test design, participants demonstrated improvements ($P < 0.05$) in health behaviors (exercise, diet, practice of relaxation techniques, examining feet, and communication with provider) and health status (self-reported health, fatigue, physical discomfort, health distress, and role/activity limitations) (18).

The SDSMP is a 6-week program offered 2.5 h weekly by two peer leaders. Programs were held in community settings in six San Francisco Bay Area counties. Class sizes ranged from 10 to 15 including participants' family and friends. Spanish-speaking peer leaders ($n = 43$) came from the same communities as the participants. Most had type 2 diabetes and were not health professionals. They received 4 days of training in the use of a detailed protocol (19). The study was approved by the Stanford School of Medicine Institutional Review Board.

### Automated telephone reinforcement

Each monthly automated call had three parts: *1*) participants were greeted and asked to rate how certain they were that they could manage their diabetes in the next month; *2*) they were given their choice of listening or not listening to 2 90-s vignettes about various aspects of diabetes, and each of 15 vignettes was offered twice over 15 months—participants might hear about how Alexandra solved problems eating with her family or how Jose talked to his doctor about impotence; and *3*) participants were invited to leave a message. If necessary, a staff member responded to these messages.

### Participants and data collection

Participants were 18 years or over, not pregnant or in care for cancer, and had type 2 diabetes. There were no other inclusion or exclusion criteria. The study was advertised in the community by word of mouth, by announcements in churches, in clinics, and by Spanish-language mass media. Potential participants contacted the study via a toll-free Spanish telephone line, were told about the study, and were asked to complete consent and baseline questionnaires either by phone or mail. Participants' physicians verified their diagnoses. One week before the beginning of each program, metabolic data (A1C) were obtained by project staff at the program sites.

Following baseline data collection, most study participants were randomized to three groups: the SDSMP with monthly automated telephone reinforcement, the SDSMP without reinforcement, or the usual-care wait-list control group. Usual care ranged from community clinics to specialist care and was representative of care received by Spanish speakers in large urban areas.

**Randomized study.** The randomized controlled study compared the SDSMP without reinforcement to the usual-care control group at 6 months. After 6-month data collection, control subjects were offered the SDSMP. Those receiving reinforcement were excluded from the 6-month randomized study in order to avoid confounding the effects of the SDSMP and the reinforcement.

**Longitudinal follow-up.** Participants in the randomized study were followed for an additional year and completed an 18-month questionnaire. This follow-up allowed the testing of whether improvements noted at 6 months would be retained at 18 months. The longitudinal participants included former control subjects who had subsequently taken the SDSMP. For the former control subjects, the 6-month questionnaire from the randomized comparison was used as a baseline, and a follow-up questionnaire was administered 18 months after enrolling in the program. Those who enrolled in the last 20 months were not included in the longitudinal follow-up, and former control subjects who had subsequently been randomized to reinforcement were also not included.

**Reinforcement study.** Participants in the 18-month reinforcement study had all participated in the SDSMP and were randomized to receive monthly automated telephone reinforcement or no reinforcement. Participants included SDSMP participants who were initially randomized to treatment plus reinforcement or control subjects from the randomized SDSMP study who then participated in the SDSMP. These control subjects were randomized to either reinforcement or no reinforcement when they completed the SDSMP. At four sites, we were unable to recruit enough people to both hold a viable program and to randomize to SDSMP or control status. These participants all enrolled in the SDSMP and were only included in the reinforcement study. Thus, most of the control group for the reinforcement study (i.e., SDMSP without reinforcement) were also the treatment group for the randomized 6-month study.

### Measures

Health status, health behaviors, health care utilization, and self-efficacy were measured at each time point. The specific measures were based on diabetes-related problems identified in participant focus groups and by self-efficacy theory (20). The Spanish measures were translated, back translated, and standardized using a consensus meeting of all translators. Measures then underwent standard psychometric testing including internal consistency and test-retest reliability, item convergent, and discriminate validity (21). A1C was measured using self-administered BIOSAFE kits. These have an expected normal range of 3.8–5.9 compared with 4–6 for the National Glycohemoglobin Standardization Program (NGSP) (22). These assays have been shown to be reliable and valid (23). Symptoms of hyper- and hypoglycemia were measured using scales developed by Piette (24). The activity limitation scale, which measures the impact of disease on role activities, was developed for an earlier study and validated in Spanish (21). Fatigue was measured using a visual numeric scale (25). Health-related distress was measured by the health distress scale adopted from the Medical Outcome Study (26,27). A single item from the National Health Survey measured self-rated health (28,29). Health behaviors were assessed by a physical activities scale measuring total minutes per week of aerobic and nonaerobic exercise (27) and by weekly frequency of glucose monitoring. A four-item scale measured communication with physicians (27). In a pilot study of Spanish-speaking people with diabetes, the communication-with-physicians scale had an $\alpha$ coefficient of 0.80 ($n = 147$) and a test/retest validity of 0.86 ($n = 20$). Self-efficacy was measured using the Spanish diabetes self-efficacy scale ($\alpha = 0.85$) and a test/retest validity of 0.80 ($n = 20$).

Health care utilization over the prior 6 months was measured by self-report. In a study evaluating the validity of self-report comparing self-reported utilization

**Table 1—*Baseline means and 6-month changes in the randomization study***

| | Baseline | | | 6-Month change scores | | |
|---|---|---|---|---|---|---|
| | Usual care | SDSMP | *P* | Usual care | SDSMP | *P* |
| *n* | 198 | 219 | | 173 | 179 | |
| Demographic variables | | | | | | |
| Age (years) (range 21–84) | 52.8 ± 13.4 | 52.9 ± 13.2 | 0.973 | | | |
| Female sex (%) | 67.2 | 57.1 | 0.034 | | | |
| Education (years) (range 0–20) | 7.30 ± 4.54 | 7.68 ± 4.49 | 0.394 | | | |
| Marriage status (% married) | 63.6 | 66.7 | 0.518 | | | |
| Born in Mexico (%) | 69.2 | 75.8 | 0.131 | | | |
| Baseline weight (kg) | 77.9 ± 13.4 | 80.0 ± 18.5 | 0.106 | | | |
| Insulin usage (%) | 12.1 | 8.7 | 0.523 | | | |
| Health indicators | | | | | | |
| A1C (%) ↓ | 7.38 ± 1.87 | 7.44 ± 2.00 | 0.765 | −0.050 ± 1.57 | −0.408 ± 1.42 | 0.040 |
| Health distress (0–5) ↓ | 2.31 ± 1.28 | 2.50 ± 1.25 | 0.158 | −0.089 ± 1.29 | −0.595 ± 1.30 | 0.009 |
| Self-reported global health (0–5) ↓ | 3.66 ± 0.821 | 3.73 ± 0.745 | 0.335 | −0.023 ± 0.807 | −0.128 ± 1.30 | 0.713 |
| Symptoms of hypoglycemia (0–12) ↓ | 2.24 ± 1.75 | 2.40 ± 1.84 | 0.738 | 0.029 ± 1.46 | −0.453 ± 1.80 | 0.042 |
| Symptoms of hyperglycemia (0–12) ↓ | 2.51 ± 2.06 | 2.58 ± 2.08 | 0.714 | 0.029 ± 2.09 | −0.827 ± 2.11 | <0.001 |
| Activity limitation (0–4) ↓ | 1.30 ± 1.18 | 1.07 ± 0.978 | 0.036 | −0.119 ± 1.12 | −0.149 ± 1.05 | 0.273 |
| Fatigue (0–10) ↓ | 4.69 ± 3.14 | 4.77 ± 3.05 | 0.810 | −0.145 ± 3.48 | −0.254 ± 3.08 | 0.694 |
| Health behaviors | | | | | | |
| Aerobic exercise (min/week) ↑ | 110.8 ± 101 | 102.0 ± 104 | 0.384 | −3.47 ± 115 | 3.60 ± 107 | 0.891 |
| Stretching/strength exercise (min/week) ↑ | 36.6 ± 56.4 | 35.6 ± 57.5 | 0.862 | 1.04 ± 72.7 | 9.52 ± 8.96 | 0.105 |
| Communication with physician (0–5) ↑ | 1.88 ± 1.41 | 1.89 ± 1.32 | 0.978 | 0.144 ± 1.34 | 0.324 ± 1.45 | 0.139 |
| Test glucose (times/week) ↑ | 0.783 ± 0.413 | 0.807 ± 0.395 | 0.537 | 0.080 ± 0.365 | 0.050 ± 0.387 | 0.457 |
| Self-efficacy (1–10) ↑ | 6.29 ± 2.14 | 6.51 ± 2.14 | 0.278 | 0.004 ± 2.37 | 0.695 ± 2.36 | <0.001 |
| Health care utilization (past 6 months) | | | | | | |
| Physician visits | 2.92 ± 2.51 | 2.75 ± 2.41 | 0.462 | −0.064 ± 2.64 | −0.028 ± 3.14 | 0.852 |
| Emergency visits | 0.389 ± 1.16 | 0.339 ± 0.783 | 0.589 | −0.081 ± 0.943 | −0.107 ± 0.820 | 0.665 |
| Days in hospital | 0.429 ± 1.72 | 0.500 ± 2.57 | 0.740 | −0.087 ± 1.49 | 0.354 ± 7.18 | 0.262 |

Data are means ± SD. The range and direction are given with each variable, where applicable: ↑, higher value is desirable; ↓ lower value is desirable. Baseline *P* values are from *t* tests comparing the two groups. Change-score *P* values compare least-squares means at 6 months after controlling for baseline value of the outcome and demographic variables as covariates in ANCOVA models.

with chart audit (30), there were no biases toward improved reporting over time.

### Data analysis

Baseline comparison of SDSMP intervention participants versus usual-care control subjects was performed using *t* tests. Variables demonstrating significant differences were included as covariates in multivariate analyses of 6-month outcomes. Those who failed to complete the 6-month questionnaire were then compared at baseline with those who had completed questionnaire using *t* tests.

At 6 months, ANCOVAs were used to compare treatment versus control groups. Demographic variables and the outcome variable at baseline were used as controlling covariates in ANCOVA models. Randomization was the factor variable, and dependent variables were 6-month outcomes. Least-square means (adjusted for covariates) were computed to determine whether there were significant differences. For all who had taken the SDSMP intervention (including control subjects who took the intervention after 6 months) and had not received reinforcement, 18-month scores were compared with baseline using paired *t* tests.

SDSMP-plus-reinforcement participants were compared with nonreinforced SDSMP participants at 18 months using ANCOVA models. Demographic and baseline values of the outcome variables were used as covariates, and least-square means were computed and tested for significant differences.

## RESULTS

### Participants

Although participants in the 6-month randomized study and the randomized telephone reinforcement study were recruited from the same pool of interested applicants and overlap, the two studies were separate, and some participants were recruited for one and not the other study. Supplemental figs. 1 and 2 (available in an online appendix at http://dx.doi.org/10.2337/dc07-1313) show the distribution of participants in the two studies.

**Randomized 6-month study.** Forty-six SDSMP workshops were held between 2002 and 2005. Of 533 individuals who completed the consent form and a baseline questionnaire, 198 were randomized to the usual-care group and 335 to the SDSMP. SDSMP participants (excluding the earliest and the last groups) were further randomized to receive telephone reinforcement or no reinforcement. The nonreinforcement group included most of the intervention group for the randomized study ($n = 219$), while the telephone reinforcement group was excluded from the randomized 6-month study ($n = 116$). At 6 months, 173 control subjects (87%) completed follow-up questionnaires, as well as 179 (82%) intervention participants. Study participants had a mean age of 52.9 years and mean years of education of 7.5, and 62% were female.

**Table 2—*Eighteen-month follow-up and changes after intervention in non-reinforced Spanish diabetes program participants***

| | Change | *P* |
|---|---|---|
| *n* | 146 | |
| Health indicators | | |
| A1C (%) ↓ | −0.319 ± 1.69 | 0.030 |
| Health distress (0–5) ↓ | −0.561 ± 1.98 | <0.001 |
| Self-reported global health (0–5) ↓ | −0.336 ± 0.942 | <0.001 |
| Symptoms of hypoglycemia (0–12) ↓ | −0.438 ± 1.71 | 0.002 |
| Symptoms of hyperglycemia (0–12) ↓ | −0.473 ± 1.97 | 0.005 |
| Activity limitation (0–4) ↓ | −0.046 ± 1.10 | 0.617 |
| Fatigue (0–10) ↓ | −0.448 ± 2.99 | 0.073 |
| Health behaviors | | |
| Aerobic exercise (min/week) ↑ | 15.4 ± 113 | 0.103 |
| Stretch/strength exercise (min/week) ↑ | 10.8 ± 69.6 | 0.063 |
| Communication with physician ↑ | 0.411 ± 1.45 | <0.001 |
| Test glucose (times/week) ↑ | 0.021 ± 0.343 | 0.477 |
| Self-efficacy (1–10) ↑ | 0.818 ± 1.79 | <0.001 |
| Utilization (past 6 months) | | |
| Physician visits | −0.490 ± 3.18 | 0.066 |
| Emergency visits | −0.181 ± 0.929 | 0.021 |
| Days in hospital | 0.451 ± 7.74 | 0.485 |

Data are means ± SD. The range and direction are given with each variable, where applicable: ↑, higher value is desirable; ↓ lower value is desirable. *P* values are from paired *t* test comparing baseline with 18-month scores.

There was a significant difference in the percentage of female participants between the control and intervention groups (67.2 vs. 57.1%, $P = 0.034$; Table 1). The only outcome with significant baseline difference was activity limitation ($P = 0.036$), and the usual-care control group had greater limitation ($P = 0.036$).

**Longitudinal 18-month (nonreinforced) follow-up.** A total of 54 control subjects and 152 intervention participants took part in the SDSMP at least 20 months before the end of the 4-year study period and did not receive telephone reinforcement. Of these 206 eligible SDSMP participants, 146 (71%) completed the 18-month follow-up questionnaire.

**Eighteen-month randomized telephone reinforcement study.** A total of 387 participants took part in the SDMSP at least 20 months before the end of the 4-year study period. Of those, 184 were randomized to receive telephone reinforcement and 203 received no reinforcement. At 18 months, 149 (73.4%) nonreinforced SDSMP participants and 151 (82.1%) reinforced participants completed questionnaires. The telephone reinforcement study participants had a mean age of 52.1 years and mean years of education of 7.5, and 62% were female. There was a significant difference in the percentage of women at baseline: 68% for the reinforced versus 56% for nonreinforced ($P = 0.012$). None of the other demographic or outcomes variables differed at baseline (data not shown).

## Noncompleters

**Randomized 6-month study.** Comparing study participants who completed 6-month questionnaires ($n = 352$) with those who did not ($n = 65$), the noncompleters did not differ significantly on baseline demographics, although a higher proportion were unmarried (45 vs. 37%, $P = 0.070$). They also had higher A1C, lower self-reported health, and more fatigue ($P = 0.034$, 0.020, and 0.037, respectively). There was also a tendency for noncompleter communication with physicians to be lower and emergency visits and days in a hospital to be higher ($P = 0.063$, 0.096, and 0.054, respectively). When comparing baseline variables of intervention 6-month noncompleters with usual-care control 6-month noncompleters, there were no significant differences except that intervention noncompleters were more educated (8.3 vs. 6.2 years, $P = 0.048$). The proportion of intervention noncompleters compared with that of usual-care control noncompleters was not statistically significant.

**Longitudinal 18-month (nonreinforced) follow-up.** Comparing those eligible but not completing 18-month questionnaires with those who did, two outcomes were significantly different. Noncompleters had more symptoms of hyper- and hypoglycemia ($P = 0.045$ and 0.005, respectively). There was also a tendency for the noncompleters to be younger (mean age 49.9 vs. 53.6 years, $P = 0.068$).

**Eighteen-month randomized telephone reinforcement study.** At baseline, those in the telephone reinforcement study not completing 18 months were more likely to be younger and male ($P = 0.028$ and 0.001, respectively). They had more symptoms of hypoglycemia and were less likely to be testing for glucose ($P = 0.012$ and 0.031, respectively). The noncompleters also tended toward more aerobic exercise, stretching, and strengthening exercise and had more symptoms of hyperglycemia ($P = 0.066$, 0.060 and 0.088, respectively). Comparing noncompleters randomized to telephone reinforcement with those randomized to no reinforcement, the only statistically significant difference was that those randomized to telephone reinforcement had more symptoms of hyperglycemia ($P = 0.050$).

## Outcomes

**Randomized 6-month study.** Because of baseline differences between intervention and control groups, baseline activity limitation was included as a covariate in all ANCOVA models. Comparing the intervention group with the usual-care control group, A1C, health distress, and symptoms of hypo- and hyperglycemia demonstrated statistically significant improvement favoring the intervention group. Intervention participants had a decrease in A1C of 0.41%, while the usual-care control subjects had a reduction of 0.05%. Of people in the treatment group entering the study with an A1C of ≥7% ($n = 101$), 30% were at <7 at 6 months (compared with 22% for control subjects). The differences in the change scores for all health status variables were in the hypothesized direction. There were no significant differences between groups in health behaviors, BMI, insulin use, or health care utilization. Self-efficacy was significantly improved for the intervention group compared with usual-care control subjects (Table 1, $P < 0.001$).

**Longitudinal 18-month follow-up.** Paired *t* tests determined whether there were improvements from baseline to 18 months for those who had participated in the intervention (Table 2). Five of seven health indicators demonstrated statisti-

**Table 3—*Eighteen-month changes in reinforced versus unreinforced intervention SDSMP participants***

| | Automated telephone reinforcement | No automated telephone reinforcement | *P* |
|---|---|---|---|
| *N* | 149 | 151 | |
| Health indicators | | | |
| A1C (%) ↓ | −0.014 ± 1.70 | −0.194 ± 1.79 | 0.298 |
| Health distress (0–5) ↓ | −0.227 ± 1.54 | −0.551 ± 1.42 | 0.120 |
| Self-reported global health (0–5) ↓ | −0.277 ± 0.925 | −0.311 ± 0.967 | 0.680 |
| Symptoms of hypoglycemia (0–12) ↓ | −0.651 ± 1.90 | −0.325 ± 1.59 | 0.389 |
| Symptoms of hyperglycemia (0–12) ↓ | −0.309 ± 1.99 | −0.457 ± 1.93 | 0.700 |
| Activity limitation (0–4) ↓ | 0.034 ± 1.15 | −0.011 ± 1.10 | 0.582 |
| Fatigue (0–10) ↓ | −0.095 ± 3.52 | −0.413 ± 3.13 | 0.859 |
| Health behaviors | | | |
| Aerobic exercise (min/week) ↑ | 23.8 ± 129 | 23.8 ± 113 | 0.565 |
| Stretch/strength exercise (min/week) ↑ | 14.2 ± 70.7 | 12.5 ± 69.9 | 0.597 |
| Communication with physician ↑ | 0.282 ± 1.43 | 0.431 ± 1.44 | 0.778 |
| Test glucose (times/week) ↑ | 0.107 ± 0.332 | 0.027 ± 0.347 | 0.001 |
| Self-efficacy (1–10) ↑ | 0.680 ± 2.13 | 0.721 ± 1.88 | 0.570 |
| Utilization (past 6 months) | | | |
| Physician visits | −0.557 ± 3.43 | −0.453 ± 3.09 | 0.682 |
| Emergency visits | 0.013 ± 0.937 | −0.193 ± 0.910 | 0.236 |
| Days in hospital | −0.134 ± 2.04 | 0.060 ± 3.74 | 0.096 |

Data are means ± SD. The range and direction are given with each variable, where applicable: ↑, higher value is desirable; ↓ lower value is desirable. Probabilities compare least-squares means at 18 months after controlling for baseline value of the outcome and demographic variables as covariates in ANCOVA models.

cally significant improvement (A1C, health distress, self-reported health, and symptoms of hypo- and hyperglycemia). Communication with physician was significantly improved, while stretching and strengthening exercise was marginally improved ($P = 0.063$). Emergency visits (in the past 6 months) decreased significantly to a mean of 0.18 days, while there were 0.49 fewer physician visits in the past 6 months ($P = 0.066$). Self-efficacy remained significantly improved.

**Eighteen-month randomized telephone reinforcement study.** The 184 SDSMP participants who were randomized to receive 15 monthly automated telephone reinforcement calls completed a mean 10.7 calls and listened to a mean 11.9 recorded vignettes. The reinforcement was suspended for 34 participants because of disconnected phones or at their request. Two participants never completed any calls. The remaining 148 averaged 12.5 completed calls (SD 4.4). Eighty-one reinforcement participants left a total of 211 messages. Over 90% of the messages conveyed appreciation for the continuing contact. The remaining calls commented on a problem or requested additional help.

Comparing those who received automated telephone reinforcement with those who did not, there was only one significant difference. Those in the telephone reinforcement group were more likely to have monitored their glucose in the last week (Table 3). There was a tendency for fewer hospital days for those with reinforcement ($P = 0.096$).

The data were rerun with number of completed calls included as a covariate with virtually identical results. The number of completed calls was not correlated with any of the 18-month outcome change scores except for greater number of visits to physicians ($r = 0.21$, $P = 0.011$).

## CONCLUSIONS

### Limitations

Because SDSMP participants could not be blinded, there is the possibility of an attention effect. However, since the telephone reinforcement appeared to have limited effect, and the improvements seen in the first 6 months were retained over 18 months, it seems unlikely that the results could be purely the result of attention.

Although the noncompletion rate was moderately high, we observed few differences at baseline between those who completed and did not complete the 6-month questionnaire. Noncompleters appeared to have more health problems. Thus, it is possible that those who had negative results following the intervention were more likely to not complete questionnaires. Because there were no differences in the baseline outcome variables between the 6-month intervention noncompleters and usual-care control group noncompleters, this likely was not an important factor affecting the 6-month randomized study. More caution must be exercised in considering the 18-month outcomes, as there was no control group for comparison.

With a largely self-selected sample, we cannot claim that our sample of Hispanics with diabetes is representative of a larger population. A comparison of a few characteristics of our sample with Latino diabetic individuals in Santa Clara County suggests that our participants were more likely to be obese and more active and were about as likely to have had a foot exam (31).

### Cost-effectiveness

The direct costs of the SDSMP are approximately $250 per participant. Gilmer et al. (32) have demonstrated that as A1C increases, health care costs increase. Wagner et al. (33) have suggested that lowering of A1C results in lower health care costs. The present study suggested significant reductions in A1C and emergency department use over 18 months. While we did not attempt cost-benefit analyses, past studies and present evidence suggest that the SDSMP may be a cost-effective intervention. This aspect of the intervention merits further study.

### Six-month randomized study

The results strongly support the hypotheses that the SDSMP resulted in improved A1C and health status indicators. However, the hypothesis of increases in positive health behaviors was not supported. One possible reason for this unexpected finding is that the SDSMP encourages participants to choose behaviors that are "right" for them—to self-tailor the intervention to their own needs. Thus, different participants choose different behaviors, making it difficult to find statistically significant changes in individual behaviors. Self-efficacy was strongly improved by participation in the SDSMP intervention and is likely to have contributed to positive health outcomes.

### Longitudinal 18-month follow-up

After 18 months, SDSMP participants continued to show improvements in health status and self-efficacy. They also demonstrated improvements in communication with their physicians and decreased emergency department visits. Although caution must be exercised in interpreting this data because of the unknown effect of noncompleters, the results suggest that the intervention continued to have positive effects 18 months later.

### Eighteen-month telephone reinforcement trial

Although participants expressed satisfaction with automated telephone reinforcement, there appeared to be little additional benefit compared with the SDSMP without reinforcement. The SDSMP alone appears to be sufficient to promote improvements in health status. Future studies might explore the effectiveness of face-to-face reinforcement.

### Summary

The randomized trial suggests that a peer-led diabetes self-management intervention held in community settings can improve A1C and quality of life and that these effects can persist for 18 months. Contrary to expectations, automated telephone reinforcement did not improve the effectiveness of the SDSMP. It is possible that a more personalized and interactive reinforcement may have been more effective. Given the high needs of the Spanish-speaking population, the dearth of effective replicable programs, and the relatively low cost of the SDSMP, we suggest that this intervention deserves consideration for implementation and further study.

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