

Online Diabetes Self-Management Program

A randomized study

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OBJECTIVE — We hypothesized that people with type 2 diabetes in an online diabetes self-management program, compared with usual-care control subjects, would 1) demonstrate reduced A1C at 6 and 18 months, 2) have fewer symptoms, 3) demonstrate increased exercise, and 4) have improved self-efficacy and patient activation. In addition, participants randomized to listserve reinforcement would have better 18-month outcomes than participants receiving no reinforcement.

RESEARCH DESIGN AND METHODS — A total of 761 participants were randomized to 1) the program, 2) the program with e-mail reinforcement, or 3) were usual-care control subjects (no treatment). This sample included 110 American Indians/Alaska Natives (AI/ANs). Analyses of covariance models were used at the 6- and 18-month follow-up to compare groups.

RESULTS — At 6 months, A1C, patient activation, and self-efficacy were improved for program participants compared with usual care control subjects ($P < 0.05$). There were no changes in other health or behavioral indicators. The AI/AN program participants demonstrated improvements in health distress and activity limitation compared with usual-care control subjects. The subgroup with initial A1C $>7\%$ demonstrated stronger improvement in A1C ($P = 0.01$). At 18 months, self-efficacy and patient activation were improved for program participants. A1C was not measured. Reinforcement showed no improvement.

CONCLUSIONS — An online diabetes self-management program is acceptable for people with type 2 diabetes. Although the results were mixed they suggest 1) that the program may have beneficial effects in reducing A1C, 2) AI/AN populations can be engaged in and benefit from online interventions, and 3) our follow-up reinforcement appeared to have no value.

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Type 2 diabetes affects 9.6% of the adult population, and its prevalence is increasing (1). While the need for self-management support is well documented, most diabetes education studies have taken place in clinical settings and targeted those who have a high A1C (usually $\geq 7\%$). Recent community-level, peer-led, small-group diabetes self-management programs have shown promise (2,3). However, not all patients

with type 2 diabetes are willing or able to participate in small-group programs, nor are such programs likely to be available in all locations.

There are few studies of community-based diabetes education programs for American Indians/Alaskan Natives (AI/ANs). We report on a randomized, controlled trial of an Internet-based diabetes self-management program (IDSMP) including AI/ANs. This was the first study,

to our knowledge, examining such a program among AI/ANs.

The Cochrane Collaboration reviewed group-based training for type 2 diabetes (4). They found 11 studies that met their criteria. Eight of these were randomized studies and three were controlled studies. All of the interventions were taught by health professionals. One study took place in a community setting, and one reported a mean baseline A1C $<7\%$.

Jackson et al. (5) conducted a systematic review of computer-assisted technologies in diabetes prior to 2004. They found four articles involving patient education. In an early study, (6) groups were randomized to basic diabetes information, tailored online coaching, or peer support. Improvement in health behaviors and psychological outcome were found in all three groups, with no differences between groups. Glasgow et al. (7) showed that a computer-assisted intervention was practicable and acceptable in a real-world setting and resulted in improvements in recommended services. In a low-intensity computer program study, short-term outcomes were promising but not significant (8). Wengberg (9), utilizing an computer diabetes intervention, has suggested that self-efficacy may function as a moderator for diabetes behavior change, and Gerber et al. (10) have demonstrated usability of an Internet program for young inner-city adults. In summary, Internet-based educational programs have been demonstrated to change behaviors and sometimes health status. We were unable to find computer-based studies demonstrating changes in A1C.

RESEARCH DESIGN AND METHODS

We report on a randomized 6-month trial of the IDSMP, with an 18-month follow-up. We hypothesized that participants in the IDSMP, compared with usual-care control subjects, would demonstrate 1) reduced A1C at 6 and 18 months, 2) have fewer symptoms, 3) have increased exercise, and 4) have improved self-efficacy and patient activation. We also hypothesized that par-

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ticipants randomized to a follow-up listserve, peer-support group would have better 18-month outcomes than participants receiving no follow-up.

The IDSMP

The asynchronous, 6-week, IDSMP is based on English- and Spanish-language peer-led small-group diabetes self-management programs (2,3). The IDSMP consists of six weekly sessions. Participants logged on individually to the sessions, which were available for the entire week. The topics covered are shown in online appendix Table A1 (available in the online appendix at <http://care.diabetesjournals.org/cgi/content/full/dc09-2153/DC1>).

A password-protected homepage provides access to the weekly activities, including The Learning Center, where the program content is offered in 20–30 new Web pages weekly. Each week, participants are asked to reply to a question such as “What problems do you have because of your diabetes?” and to make a specific action plan. The questions and action plans are posted on bulletin boards in the Discussion Center, where they can be seen by all participants.

The Discussion Center is made up of four interactive threaded bulletin boards (Action Planning, Problem Solving, Difficult Emotions, and Celebrations) populated by responses made in the Learning Center, as well as new threads started by participants whenever they wish. A typical program of 20–25 participants results in 500 or more posts. My Tools consists of exercise and medication logs, audio relaxation exercises, meal planning, and glucose-monitoring tools and links to other diabetes-related Web sites. Post Office is a section where participants and facilitators can write private, individual messages to each other. Help is a section where participants can e-mail the moderators or program administrators. The latter is also available via a toll-free telephone line.

In addition to the Web program, each participant received a copy of the book, *Living a Healthy Life with Chronic Conditions* (11). Specific sections of this book are referenced in the Learning Center. The book is used as a reference not as a text. Thus, the program consists of the online interactive training plus the book.

Facilitators

Two peers facilitate each program. Facilitators were previously trained as self-management small-group leaders and

had taken the IDSMP (as nonstudy subjects). Facilitators assist participants by reminding them to log on, modeling action planning and problem-solving, offering encouragement, and posting to the bulletin boards. They also monitor the daily posts for safety and report inappropriate posts to the investigators. All facilitation takes place online, mainly via posts within the program pages. Each participant receives personalized responses from facilitators during each weekly session. Unlike the small-group program, facilitators do not deliver content, as this is scripted in the Learning Center. Programs were facilitated by 16 different people, half with diabetes. Each program has at least one facilitator with diabetes. The study was approved by the Stanford School of Medicine Institutional Review Board.

Participants and data collection

Participants were aged ≥ 18 years, were not pregnant or in care for cancer, had physician-verified type 2 diabetes, and had access to the Internet. Recruitment was largely via the Internet, although print and broadcast media were also utilized. Special effort was made to recruit AI/AN participants using Web sites and media associated with tribal and AI/AN organizations. This was accomplished utilizing the expertise of an AI/AN researcher (12).

All consents and questionnaires were administered online. Participants contacted the study by going to the Web site, where they were screened for eligibility and were asked to complete consent and baseline questionnaires. A1C was obtained using mailed self-administered BIOSAFE kits (13).

After returning A1C kits, participants were randomized using a random-numbers table. Roughly two-thirds became treatment subjects and one-third continued with usual care (no program or other treatment offered). Treatment subjects were further randomized one for one to receive follow-up reinforcement (membership in a listserve discussion group) or no reinforcement. Usual care consisted of whatever care participants had been previously receiving and ranged from community clinics to specialist care. Usual-care participants were not restricted from seeking additional care or programs. All participants received a \$10 Amazon.com certificate after completing each questionnaire and returning their A1C sample.

Randomized study

The randomized IDSMP group was compared with the usual-care control group at 6 months. If the reinforcement study (below) had shown that reinforcement participants had greater improvements than unreinforced IDSMP participants, the two IDSMP groups would be compared with control participants separately. If there were few differences, the two randomized IDSMP groups would be combined and compared with the usual-care control group.

After 6 months, usual-care participants recruited as part of the AI/AN subgroup were offered the program. All other usual-care participants continued as control subjects through the 18 months of the study. Follow-up data collected at 18 months allowed comparison of IDSMP participants to usual-care subjects, excluding the AI/AN subset.

Reinforcement study

The reinforcement study compared IDSMP treatment participants who had no reinforcement with those who had been randomized to a listserve discussion group. The discussion group was intended to reinforce any benefits of the program by providing peer support. Comparisons were made at 6 and at 18 months. The AI/AN participants were included in the 18-month reinforcement study.

AI/AN study

AI/AN participants were randomized with other participants but entered the randomized study for only 6 months, after which time AI/AN usual-care participants were offered an opportunity to take the IDSMP. The lack of adequate usual medical care and chronic health disparities among the AI/AN subset, as well as the longstanding mistrust of research in many AI/AN communities, were reasons the AI/AN subset was randomized using the waitlist control design. A pilot study of 27 AI/AN and 27 non-AI/AN participants with diabetes had confirmed the feasibility of the online programs for this population (14).

Health status, health behaviors, health care utilization, patient activation, and self-efficacy were measured at each time point. The specific measures were based on diabetes-related problems identified in participant focus groups and on self-efficacy theory (15). The primary outcome measure was A1C, measured using capillary blood obtained with self-

administered BIOSAFE kits. These have an expected nondiabetic range of 3.8–5.9 compared with 4–6 for National Glycohemoglobin Standardization Program standards (16). A paired duplicate specimen comparison with the whole-blood method at Stanford Hospital Laboratories showed excellent correlation and precision. These assays have independently been shown to be reliable and valid (16). The A1C measure was not available for the 18-month comparisons because BIOSAFE ceased operation early in the 18-month data collection. Health-related distress was measured by the health distress scale, adapted from the Medical Outcome Study (17). The activity limitations scale, which measures the impact of disease on role activities such as recreation and chores, was developed for an earlier study (18). Depression was measured by the Patient Health Questionnaire (PHQ)-9 (19). A physical activities scale measured total minutes per week of aerobic exercise (18).

Tertiary measures included the 13-item short-form Patient Activation Measure (PAM) and diabetes self-efficacy. PAM measures patient self-reported knowledge, skill, and confidence for managing their chronic condition (20). The diabetes self-efficacy scale was developed for a small-group diabetes program (2) and based on earlier chronic-disease self-efficacy scales (18).

Health care utilization over the prior 6 months was measured by self-report. In a study comparing the validity of self-reported with chart audit (21), there were no biases toward improved reporting over time. Details of the psychometric properties for most of the measures can be found at <http://patienteducation.stanford.edu/research>.

Data analysis

Baseline randomization. *T* tests were used to compare baseline IDSMP participants with usual-care participants and to compare baseline reinforced with unreinforced IDSMP participants. We included all variables demonstrating significant differences at baseline as covariates in subsequent multivariate analyses at 6 and 18 months.

Noncompleters. To test the potential effect of dropouts, we compared the baseline variables for those who failed to complete the 6-month questionnaires with those who had completed questionnaires, utilizing *t* tests. Control versus

treatment noncompleters were then compared.

Reinforcement. ANCOVA models were used to compare reinforced with unreinforced program participants. Six- and 18-month outcomes were the dependent variables with demographic variables and the outcome variable at baseline included as covariates. Least-square means (computed as part of the ANCOVA procedure and adjusted for covariates) were used to determine if there were significant differences between the treatment groups randomized to reinforcement and no reinforcement.

Six-month outcomes. ANCOVA models compared program and control participants at 6 months. As reinforcement proved to have no effect on the outcomes (see results below), reinforced and unreinforced participants were combined to create one treatment group, which was then compared with the control participants. Separate comparisons of the control subjects and reinforced and unreinforced program participants are also presented. All subjects, irrespective of the number of weeks they participated in the intervention, were included in the analyses. Least-square means (adjusted for covariates) were used to determine if there were significant differences between the program participants and the randomized usual-care control group after controlling for baseline outcome values and demographic covariates.

ANCOVA models were repeated, adding interaction terms of all baseline outcome variables with randomization. This was to ascertain if existing conditions might moderate the effectiveness of the program and help determine the characteristics of participants most likely to benefit. Analyses were done using both actual data collected and intent-to-treat methodology, based on substituting last acquired data for missing data. In the case of 6-month outcomes, this resulted in the assumption of no change from baseline. *P* values are interpreted within each category of outcome (A1C, three health indicators, one health behavior, self-efficacy, patient activation, and utilization).

Eighteen-month outcomes. Randomized program participants were compared to the usual-care control group at 18 months, using the methodology (ANCOVA) discussed above.

Subgroup analyses. Six-month analyses (ANCOVA models) comparing randomized treatment participants and usual-care control subjects were then done for

two subsets of the original study sample: AI/ANs and participants with baseline A1C $\geq 7\%$.

RESULTS

Participation

Approximately 36% of participants found the Web site through links on the Internet or search engines. Another 21% learned of the study via e-mail or e-mail newsletters; 9% were referred by relatives, friends, or coworkers; 17% were referred through print media; and 10% were referred by health professionals. The AI/AN subset discovered the study through the Web (29%, including 5% who found out about the study via tribal Web sites) and e-mail (20%). Larger numbers were referred by relatives or acquaintances (21%), and 18% found the study through print media (including 15% via AI/AN-oriented media).

A total of 1,463 people visited the Web site and left contact information (online appendix Fig. A1). Of these, 1,019 completed enrollment screening and proceeded to the baseline questionnaire. A further 48 were disqualified, 22 subsequently declined, 74 failed to complete consent or baseline questionnaires, and 104 failed to complete A1C testing. The remaining 761 participants completed baseline assessments and were randomized to one of three groups: usual-care control group (270), the online program (259), or the online program plus listserve e-mail reinforcement (232). Subsequently, 27 withdrew or dropped out and 2 died before completing the 6-month questionnaire. Thus, 732 continued in the study for 6 months. Of those continuing, 645 (85%) completed the 6-month questionnaire. These included 238 control subjects and 395 participants in the online program (109 unreinforced treatments and 186 reinforced treatments). Between August 2006 and September 2007, 21 programs were held with a mean of 23 participants per program.

The AI/AN recruitment resulted in a sample that included 110 AI/AN participants. (see online appendix Fig. A2). After 6 months, AI/AN control subjects were allowed to enroll in the program and thus were no longer part of the randomized study. Of 651 remaining (non-AI/AN) study participants, 528 (81%) completed 18-month questionnaires.

Baseline

Study participants were predominantly non-Hispanic white (76%), female (73%), married (66%), and well educated (mean of 15.7 years of education). The average age was 54.3 years. The only statistical difference between the randomized treatment and control groups was percentage married (78 vs. 71%, $P = 0.034$; online appendix Table A2). Percentage married, as well as other demographic variables, were included as covariates in subsequent ANCOVA. The control subjects had slightly higher PHQ depression levels at baseline (Table A3). The mean baseline A1C level at baseline was 6.44%, relatively low for a population with diabetes.

The AI/AN subset represented ~70 tribal groups. They were slightly younger than the non-AI/AN participants (mean age 51 vs. 55 years, $P < 0.001$) and were less likely to be married (57 vs. 68%, $P = 0.035$). Demographics for AI/ANs by randomization are given in Appendix Table A2. The AI/AN subset also had higher baseline mean A1C (6.9 vs. 6.4, $P < 0.001$). None of the other outcome variables differed significantly from non-AI/ANs at baseline.

Program usage

Case et al. (22) conducted a study of the IDSMP utilization by 45 participants (15 each African American, Non-Hispanic white, and AI/ANs). The median number of days for writing messages for all races was 32 (30 for African Americans, 37 for Non-Hispanic whites, and 28 for AI/ANs), with 80% of participants writing messages over a period of at least 21 days or half the length of the workshop. The median number of messages per participant was 17 and the mean was 25. There were few differences among the racial groups, although AI/ANs logged for a shorter time period than non-Hispanic whites. There were few differences in the content of the posts.

Six-month noncompleters

There were few significant differences at baseline between those who completed 6-month questionnaires and those who did not. Noncompleters were younger, less likely to be married, and less likely to be non-Hispanic white. They had higher mean baseline A1C and higher levels of health distress. However, there were no significant differences between the participant noncompleters and the usual-care

control noncompleters (see online appendix Table A4).

Six-month randomized outcomes

Table 1 provides information regarding the changes in outcome variables for the control and treatment participants. Because reinforcement was not associated with any improvements (see below under REINFORCEMENT STUDY), the two treatment groups were combined for the 6-month comparison to usual-care control subjects, as well as kept separate. Treatment participants, when compared with usual-care control subjects, had significantly lower A1C ($P < 0.05$) as well as improvements in patient activation (PAM) and self-efficacy (0.021 and <0.001 , respectively). Health behavior and utilization changes were not significantly different for treatment compared with control group participants. When intent-to-treat analyses were used, PAM and self-efficacy remained significant, while the P value for A1C increased to 0.060.

When ANCOVAs were rerun with baseline randomization interaction terms included in the models, the interaction of A1C with randomization was significant in predicting 6-month A1C ($P < 0.001$). AI/AN versus non-AI/AN interactions with randomization were significant in predicting 6-month health distress, activity limitation, and physician visits. These two initial conditions were then examined in more detail below. Baseline self-efficacy also had significant interactions with randomization and appears to be a moderating variable, suggesting that lower baseline self-efficacy was associated with better outcomes. This will be examined elsewhere.

Eighteen-month randomized outcomes

The comparison of 18-month completers to noncompleters showed few differences: the noncompleters were younger, had higher A1C, and higher health distress at baseline (online appendix Table A8). There were no significant differences between the participant and usual-care control noncompleters. We could not include A1C analyses at 18 months because of the closure of the laboratory. Results from a second laboratory could not be adequately correlated with the original lab. Of the remaining outcome variables, two had significantly greater improvements for program participants as compared with the usual-care participants: self-efficacy to manage diabetes and PAM pa-

tient activation ($P = 0.016$, 0.007, respectively; online appendix Table A6). Other 18-month change score differences were not significant. Intent-to-treat methodology resulted in the P value for PAM increasing to 0.052.

Reinforcement study

Online appendix Fig. A3 gives information about the participants in the reinforcement study. At 6 months, there was only one significant difference between reinforced ($n = 186$) and unreinforced ($n = 209$) participants. The unreinforced participants had greater improvement in health distress ($P = 0.007$; online appendix Table A7). At 18 months, there again was one variable that was significantly different. The unreinforced participants had a greater reduction in depression ($P = 0.033$; online appendix Table A8). Intent-to-treat methodology did not change the results.

High A1C subgroup

When only participants with baseline A1C $\geq 7.0\%$ are included at 6 months (online appendix Table A9), the difference between treatment and control for A1C was 0.614 ($P = 0.010$, effect size 0.499). Self-efficacy was also statistically significant ($P = 0.040$), although the effect size was small.

AI/AN subgroup

At 6 months, the AI/AN subsample was underpowered ($n = 73$). Despite the low number of cases, there were significant decreases in health distress and activity limitation for AI/AN program participants compared with control subjects (Table 2). While not statistically significant, the A1C change score difference between the two groups was nearly 0.3. The treatment group had a statistically significant increase in physician visits. Using intent-to-treat methodology, activity limitation remained significant, while health distress and physician visits became marginal. Tables A10 and A11 in the online appendix present the 6-month data for AI/ANs and non-AI/ANs separately.

CONCLUSIONS — At 6 months, results were mixed. The changes in the primary outcome variable (A1C) had a small (effect size = 0.111) but statistically significant difference between treatment and usual-care control groups when only looking at actual cases ($P = 0.039$). The two tertiary outcomes, patient activation and self-efficacy, both improved for treat-

Table 1—Six-month change scores, diabetes online, all participants

Outcome variable	Treatment, no reinforcement		Treatment and reinforcement		Treatment combined		T vs. control		R vs. control		R vs. T		C vs. treatment (T + R)	
	Control	T	R	T plus R	P (ITT)	P (ITT)	P (ITT)	P (ITT)	P (ITT)	P (ITT)	P (ITT)	P (ITT)	P (ITT)	P (ITT)
n	238	209	186	395										
A1C ↓	0.126 ± 0.779	-0.034 ± 0.844	0.018 ± 0.862	-0.009 ± 0.852	0.064	0.036	0.176	0.162	0.653	0.530	0.060	0.039		
Health distress (0–5) ↓	-0.257 ± 0.844	-0.348 ± 1.03	-0.082 ± 0.988	-0.203 ± 1.02	0.231	0.078	.089	0.168	0.005	0.003	0.822	0.771		
Activity limitation (0–4) ↓	0.034 ± 0.848	-0.019 ± 0.869	0.009 ± 0.982	-0.006 ± 0.923	0.217	0.200	0.453	0.425	0.655	0.664	0.243	0.219		
PHQ depression (0–27) ↓	-0.836 ± 3.82	-1.072 ± 4.44	-0.398 ± 4.10	-0.754 ± 4.26	0.413	0.183	0.465	0.687	0.131	0.099	0.931	0.558		
PAM patient activation (0–100) ↑	3.63 ± 14.4	6.24 ± 14.5	5.09 ± 14.3	5.70 ± 14.4	0.083	0.035	0.230	0.069	0.631	0.827	0.085	0.021		
Self-efficacy (1–10) ↑	-0.203 ± 1.70	0.321 ± 1.99	0.160 ± 1.73	0.245 ± 1.87	<0.001	<0.001	0.004	0.001	0.656	0.760	<0.001	<0.001		
Aerobic exercise (min/week) ↑	-1.97 ± 130	12.09 ± 145	1.41 ± 167	7.04 ± 156	0.496	0.238	0.799	0.306	0.687	0.905	0.579	0.194		
Physician visits (last 6 months)	-0.198 ± 3.25	-0.121 ± 3.53	-0.239 ± 3.55	-0.177 ± 3.54	0.809	0.679	0.722	0.611	0.906	0.967	0.730	0.589		

Data are outcome variable (possible ranges). P values are from ANCOVA models controlling for baseline outcome variable and demographic variables and assess the likelihood that there would have been no difference between the treatment and control group. Arrows indicate desirable directions. ITT, intent to treat, baseline value carried forward (no change) for missing 6-month outcomes; T, treatment program without reinforcement; R, treatment program with listserve peer-support reinforcement. Possible ranges are given in parentheses next to outcome variable names; and arrows indicate desirable directions. Significant P-values are bolded.

ment participants compared with usual-care control subjects. However secondary outcomes did not improve. None of the three health indicators showed significant differences, nor were the amount of exercise or number of physician visits significantly changed. At 18 months, PAM patient activation and self-efficacy were significantly increased for program participants, although PAM became marginal when intent-to-treat methodology was used. Other outcomes variables were not significant at 18 months. Randomization to listserve e-mail peer-support reinforcement did not improve the outcomes for program participants, either at 6 or 18 months.

Surprisingly the attempt at reinforcement was not effective. We encountered a similar finding in another study, using a different reinforcement technique (automated follow-up phone calls) (3). Further study, including more attention to how the listserve was utilized, would be required to determine if only our particular attempts at reinforcement were unsuccessful or if follow-up in general is not called for with similar self-management programs. In addition, further study of program fidelity and how program participants utilized the program, including any possible dose effect, would be desirable. The lack of a detailed analysis of effects of program utilization, as well as analyses of possible mediating effects of secondary and tertiary variables, is an important limitation but was beyond the scope of this study.

A further limitation of the study was the relatively low mean A1C at baseline. A large portion of the participants were in control and more likely to get worse rather than better due to both a floor effect and regression to the mean. When we looked at the subgroups of those with baseline A1C >7.0% at baseline, the differences in improvements in A1C increased from a very modest effect size of 0.11 for the entire randomized sample to a clinically significant effect size of 0.50. This suggests that the program may prove more successful if targeted to patients with higher A1C.

When we limited ourselves to the AI/AN subset (who had a mean baseline A1C of nearly 7.0% compared with the total sample mean of 6.4%), we saw improvements in health indicators (activity limitations and health distress with significant effect sizes of 0.48 and 0.34, respectively). Although the difference for A1C was not statistically significant, with a

Table 2—AI/AN subgroup, baseline and 6-month changes

Outcome variable	Baseline		6-month change				
	Control	Treatment	Control	Treatment	Control vs. treatment		
					Effect size	P (ITT)	P
n	50	60	38	35			
A1C ↓	6.71 ± 1.25	7.12 ± 1.59	0.206 ± 0.973	-0.088 ± 1.24	0.251	0.288	0.379
Health distress (0–5) ↓	2.26 ± 1.24	2.06 ± 1.24	-0.151 ± 0.730	-0.714 ± 0.993	0.484	0.025	0.004
Activity limitation (0–4) ↓	1.48 ± 1.12	1.14 ± 1.03	0.092 ± 0.843	-0.257 ± 0.986	0.337	0.028	0.012
PHQ depression (0–27) ↓	8.60 ± 6.35	8.33 ± 5.67	-0.737 ± 3.84	-1.600 ± 5.33	0.146	0.677	0.214
PAM patient activation (0–100) ↑	63.3 ± 15.8	63.8 ± 14.8	4.47 ± 16.4	3.78 ± 13.3	-0.054	0.612	0.722
Self-efficacy (1–10) ↑	6.74 ± 1.86	6.39 ± 2.29	-0.056 ± 1.40	0.350 ± 2.40	0.214	0.896	0.584
Aerobic exercise (min/week) ↑	93.1 ± 133	81.2 ± 103	3.32 ± 118	18.62 ± 112	0.111	0.789	0.810
Physician visits (last 6 months)	3.42 ± 3.53	3.17 ± 3.38	-0.658 ± 1.86	0.914 ± 3.85	0.494	0.051	0.019

Data are means ± SD. Effect sizes are computed as the difference in change scores between treatment and control groups divided by the pooled baseline SD. Negative effect sizes indicate that the control group did better than the treatment group. P values are from ANCOVA models controlling for baseline outcome variable and demographic variables and assess the likelihood that there would have been no difference between the treatment and control group. Possible ranges are given in parentheses next to outcome variable names, and arrows indicate desirable directions. Significant P-values are bolded.

properly powered sample, an effect size difference of 0.25 would undoubtedly have been statistically significant.

The methods of recruitment and design of the study may have contributed to low differences between treatment and control participants. A high proportion of those who joined the study were actively seeking information about their disease when they found the study Web site. The control group was not offered the possibility of participation in the program after a short period of time and may have searched for and found alternate interventions. The AI/AN subgroup was an exception in this regard as they were offered the program after 6 months. This may have contributed to the relative success of the program within that subgroup.

Although results were both encouraging and discouraging, they suggest that the program can be beneficial to people with diabetes and that further study is warranted. A trial with broader recruitment, limited to only those with A1C >7.0%, and allowing randomized control subjects to participate in the program after a 6-month trial would prove more definitive.

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References

1. National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics fact sheet: general information and national estimates on diabetes in the United States, 2005. Washington, DC, Govt. Printing Office [NIH publ. no. 06-3892]
2. Lorig K, Ritter PL, Villa FJ, Armas J. Community-based peer-led diabetes self-management: a randomized trial. *Diabetes Educ* 2009;35:641–51
3. Lorig K, Ritter PL, Villa F, Piette JD. Spanish diabetes self-management with and without automated telephone reinforcement: two randomized trials. *Diabetes Care* 2008;31:408–414
4. Deakin T, McShane CE, Cade JE, Williams RDRR. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2005;18:CD003417
5. Jackson CL, Bolen S, Brancati FL, Batts-Turner ML, Gary TL. A systematic review of interactive computer-assisted technology in diabetes care: interactive information technology in diabetes care. *J Gen Intern Med*. 2006;21:105–10
6. Glasgow RE, Boles SM, McKay HG, Feil EG, Barrera M Jr. The D-Net diabetes self-management program: long-term implementation, outcomes, and generalization results. *Prev Med* 2003;36:410–9
7. Glasgow RE, Nutting PA, King DK, Nelson CC, Cutter G, Gaglio B, Rahm AK, Whitesides H, Amthauer H. A practical randomized trial to improve diabetes care. *J Gen Intern Med* 2004;19:1167–74

8. Glasgow RE, Nutting PA, Toobert DJ, King DK, Strycker LA, Jex M, O'Neill C, Whitesides H, Merenich J. Effects of a brief computer-assisted diabetes self-management intervention on dietary, biological and quality-of-life outcomes. *Chronic Illn*;2:27–38
9. Wangberg SC. An Internet-based diabetes self-care intervention tailored to self-efficacy. *Health Educ Res* 2008;23:170–9
10. Gerber BS, Solomon MC, Shaffer TL, Quinn MT, Lipton RB. Evaluation of an Internet diabetes self-management training program for adolescents and young adults. *Diabetes Tech Ther* 2007;9:60–67
11. Lorig K, Holman H, Sobel D, Laurent D, Gonzalez V, Minor M. *Living a Healthy Life With Chronic Conditions*. 3rd ed. Boulder, Colorado; Bull Publishing, 2006
12. Jerrigan VJ. *The Native American Diabetes Self-Management Program*. PHD thesis. Berkeley, California, University of California Berkeley, School of Public Health, unpublished
13. Tyrrell SP, Bui TL, Maggiore, JA. *Hemoglobin A1c Detection System: A Technical Bulletin Describing the Performance Characteristics of Capillary Blood Collected on Filter Paper for Determination of Hemoglobin A1c*. Chicago, BIOSAFE Laboratories, Bulletin 4018, Rev. 99037, 2006
14. Jernigan, VBB, Lorig K. The Internet Diabetes Self-Management Workshop for American Indians and Alaska Natives. Health Promotion Practice, In press
15. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev* 1977;84:191–215
16. Miedema K. Standardization of HbA1c and optimal range of monitoring. *Scand J Clin Lab Invest* 2005;65(Suppl. 240):61–72
17. Stewart AL, Ware JE. *Measuring Function-*

- ing and Well Being: The Medical Outcomes Study Approach*. Durham, NC, Duke University Press, 1992
18. Lorig K, Stewart A, Ritter P, González V, Laurent D, Lynch J. *Outcome Measures for Health Education and Other Health Care Interventions*. Thousand Oaks CA, Sage Publications, 1996
 19. Kroenke K, Spitzer RL. The PHQ-9: a new depression diagnostic and severity measure. *Psychiatr Ann* 2002;35:509–521
 20. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. *Health Serv Res* 2005;40:1918–30
 21. Ritter PL, Kaymaz H, Stewart A, Sobel DS, Lorig KR. Self-reports of health care utilization compared to provider records. *J Clin Epidemiol* 2001;54:136–141
 22. Case S, Jernigan V, Gardner A, Ritter PL, Heaney CA, Lorig KR. Content and frequency of writing on diabetes bulletin boards: does race make a difference? *J Med Internet Res* 2009;11:e22