Outcomes of Minimal and Moderate Support Versions of an Internet-Based Diabetes Self-Management Support Program

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OBJECTIVE: Internet and other interactive technology-based programs offer great potential for practical, effective, and cost-efficient diabetes self-management (DSM) programs capable of reaching large numbers of patients. This study evaluated minimal and moderate support versions of an Internet-based diabetes self-management program, compared to an enhanced usual care condition.

RESEARCH DESIGN AND METHODS: A three-arm practical randomized trial was conducted to evaluate minimal contact and moderate contact versions of an Internet-based diabetes self-management program, offered in English and Spanish, compared to enhanced usual care. A heterogeneous sample of 463 type 2 patients was randomized and 82.5% completed a 4-month follow-up. Primary outcomes were behavior changes in healthy eating, physical activity, and medication taking. Secondary outcomes included hemoglobin A1c, body mass index, lipids, and blood pressure.

RESULTS: The Internet-based intervention produced significantly greater improvements than the enhanced usual care condition on three of four behavioral outcomes (effect sizes [*d*] for healthy eating = 0.32; fat intake = 0.28; physical activity= 0.19) in both intent-to-treat and complete-cases analyses. These changes did not translate into differential improvements in biological outcomes during the 4-month study period. Added contact did not further enhance outcomes beyond the minimal contact intervention.

CONCLUSIONS: The Internet intervention meets several of the RE-AIM criteria for potential public health impact, including reaching a large number of persons, and being practical, feasible, and engaging for participants, but with mixed effectiveness in improving outcomes, and consistent results across different subgroups. Additional research is needed to evaluate longer-term outcomes, enhance effectiveness and cost-effectiveness, and understand the linkages between intervention processes and outcomes.

Electronic supplementary material *The online version of this article (doi:10.1007/s11606-010-1480-0) contains supplementary material, which is available to authorized users.*

Received February 25, 2010
Revised June 7, 2010
Accepted July 21, 2010
Published online August 17, 2010

KEY WORDS: internet; diabetes self-management; RCT; health disparities; behavior change; practical trial.
J Gen Intern Med 25(12):1315–22
DOI: 10.1007/s11606-010-1480-0

INTRODUCTION

Type 2 diabetes is a complex condition whose optimal management requires *multiple* lifestyle changes, including dietary, physical activity, medication taking, and glucose monitoring. These regimen requirements are made difficult by broader social influences, including our current "obesogenic environment."[1,2] Type 2 diabetes is increasingly prevalent and affects nearly 24 million Americans aged 20 years and older.[3] Although diabetes self-management (DSM) has been shown to be effective,[1,3,4] many patients do not receive it,[5] and the rising rates of diabetes make it imperative to find efficient, practical ways of delivering DSM.

To increase reach, various DSM modalities must be explored. Interactive computer technologies have much to offer, particularly if they incorporate theory-based principles and provide feedback and tailored information.[6,7] They can be available 24 hours a day, may be cost-effective, and have the potential of freeing clinicians to focus on other care priorities. However, most current Internet DSM programs are largely informational, at high literacy levels, and available only in English.[8] Internet research in related areas, especially weight loss, has shown that added contact—even if moderate—can increase effectiveness.[9,10] Therefore, we investigated the impact of different levels of interpersonal contact for Internet-based DSM support.

In addition to the behaviors necessary to achieve healthy weight control (i.e., physical activity and healthful eating), DSM involves other behaviors. Thus, there is also a pressing need for research on multiple-health-behavior interventions capable of being translated into practice.[11,12] Much DSM research has been conducted in academic settings, and has not addressed real-world challenges or the context of primary care practice. We addressed these issues by evaluating a practical, computer-based (combined Internet and automated telephone) DSM intervention targeting dietary and physical activity (PA) practices and medication taking.

Due to the digital divide, the reach of computer-based health promotion programs among underserved populations is in question. Latinos, compared to non-Hispanic whites, tend to have less access to the Internet and tend to use the Internet less for seeking health information.[13,14] However, as in other ethnic groups, access to computers and the Internet is related to education and socio-economic class. Limited access to technology is certainly a factor, but so is a relative scarcity of programs designed for Spanish-dominant Latinos. LUCHAR was one such program designed for Latinos that demonstrated significant improvements in nutrition and physical activity amongst the programs users.[15]

Reviews of the literature on DSM are encouraging regarding at least short-term improvements in regimen behaviors and hemoglobin A1c.[1,4,16] The longer term effects are much less consistent, and many persons do not participate in DSM education.[5,17–19] The smaller and evolving literature on Internet and computer-based DSM programs[7,8,20,21] is similarly encouraging but mixed. Key issues in need of research attention include which subgroups of patients will participate, the high rates of attrition,[22] impact across different patient subgroups and outcomes, and the amount of contact needed with live intervention staff. The present project was developed to address several of these issues.

Our overall research project aims to provide evidence on varying levels of support necessary to achieve DSM through regular physical activity, healthful eating, and appropriate medication use. The purposes of this paper were to (a) evaluate the feasibility of an Internet-based DSM program (*MyPath/Mi Camino*) using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) model[19] (www.re-aim.org); (b) present the 4-month behavioral and biological outcomes from a practical randomized trial; and (c) experimentally investigate the incremental effects of adding support to a minimal-contact version of the Internet-based program.

METHODS

A three-arm, patient-randomized practical effectiveness trial[23] evaluated two Internet-based DSM programs, relative to "enhanced" usual care (EUC). Practical effectiveness or pragmatic trials[23,24] are different from traditional efficacy studies in that they employ heterogeneous samples, studied in multiple representative settings, use outcomes important to decision and policy makers, and study real-world comparison conditions. The interventions were (a) self-administered, computer-assisted self-management (CASM), based on social-ecological theory[2] and the "5 As" self-management model,[11] and (b) the CASM program with the addition of enhanced social support (CASM+SS). EUC provided computer-based health risk appraisal feedback and recommended preventive care behaviors using the same contact schedule as CASM, but did not include the key intervention procedures. EUC participants, as well as CASM and CASM+SS participants, were eligible to participate in other traditional DMS education, such as education classes, weight loss groups, or case management available to Kaiser Permanente Colorado (KPCO) members, but very few did so during the study.

The study was conducted in five primary care clinics within Kaiser Permanente Colorado (KPCO). Clinics were selected based on variability in size, location, and socioeconomic status of neighborhood, and to maximize percentage of Latino patients. Recruitment issues are described in detail in Glasgow et al[25] and summarized in Figure 1. Eligibility criteria included: 25–75 years of age, diagnosis of type 2 diabetes, body mass index (BMI) of 25 kg/m^2 or greater, and at least one other risk factor for heart disease. Additional inclusion criteria were access to a telephone and at least biweekly access to the Internet, ability to read and write in English or Spanish, and to perform mild to moderate PA. Participants were individually randomized via a computer program developed by our computer programmer and statistician. Data were collected from April 2008 to December 2009 and analyzed in December 2009. All procedures were approved by the KPCO institutional review board.

Interventions

Interventions were available in English and Spanish, and based on refinements of interactive self-management programs found effective in prior research.[26] Both the Spanish and English versions were developed in consultation with local dieticians and leaders in culturally competent care to offer strategies and options that were appropriate for Latino or African American, in addition to Anglo participants. Both conditions featured self-pacing, "more information" text boxes, and voice-over narration to assist less health literate participants.

CASM. CASM participants were given access to the "*My Path to Healthy Life*"/"*Mi Camino A La Vida Sana*" website and instructed in website log-in, navigation, and usage by a research staff member. Participants were asked to select initial, easily achievable goals in each of three areas: medication adherence, exercise, and food choices. They recorded their progress on these three daily goals using the tracking section of the website (Online Appendix Table A1) and received immediate feedback on success meeting their goals over the past 7 days. The website, described in detail elsewhere,[27] included a graphical display of the patient's hemoglobin A1c, blood pressure, and cholesterol results; a moderated forum; and community resources (e.g., healthful recipes, printable handouts) for DSM and healthy lifestyles, as well as features to enhance user engagement, such as rotating quiz questions and motivational tips.

After 6 weeks, participants created new personalized goals and "action plans" for medication taking, healthy eating, and PA. For each of the three areas, users identified barriers to achieving the (revised) goal(s) they had selected, and then chose from a list of problem-solving strategies to overcome those barriers.[28] Each user's action plan summary (Online Appendix Table A2) was available for easy reference and/or revision.

In addition to the website, CASM participants received periodic prompting using a computer-based telephone system that initiated outbound calls, received inbound calls, provided motivational information, and collected data.

CASM+SS. CASM+SS participants received all aspects of the CASM intervention with the addition of follow-up calls from an interventionist, and were invited to attend a group visit with other participants in the same study condition. Interventionists were the same as those for the other two conditions. The four staff members had a variety of educational and experience backgrounds, ranging from bachelors degrees to an M.S. in social work, and received standardized training, including practice sessions. Two staff members who were fluent in Spanish

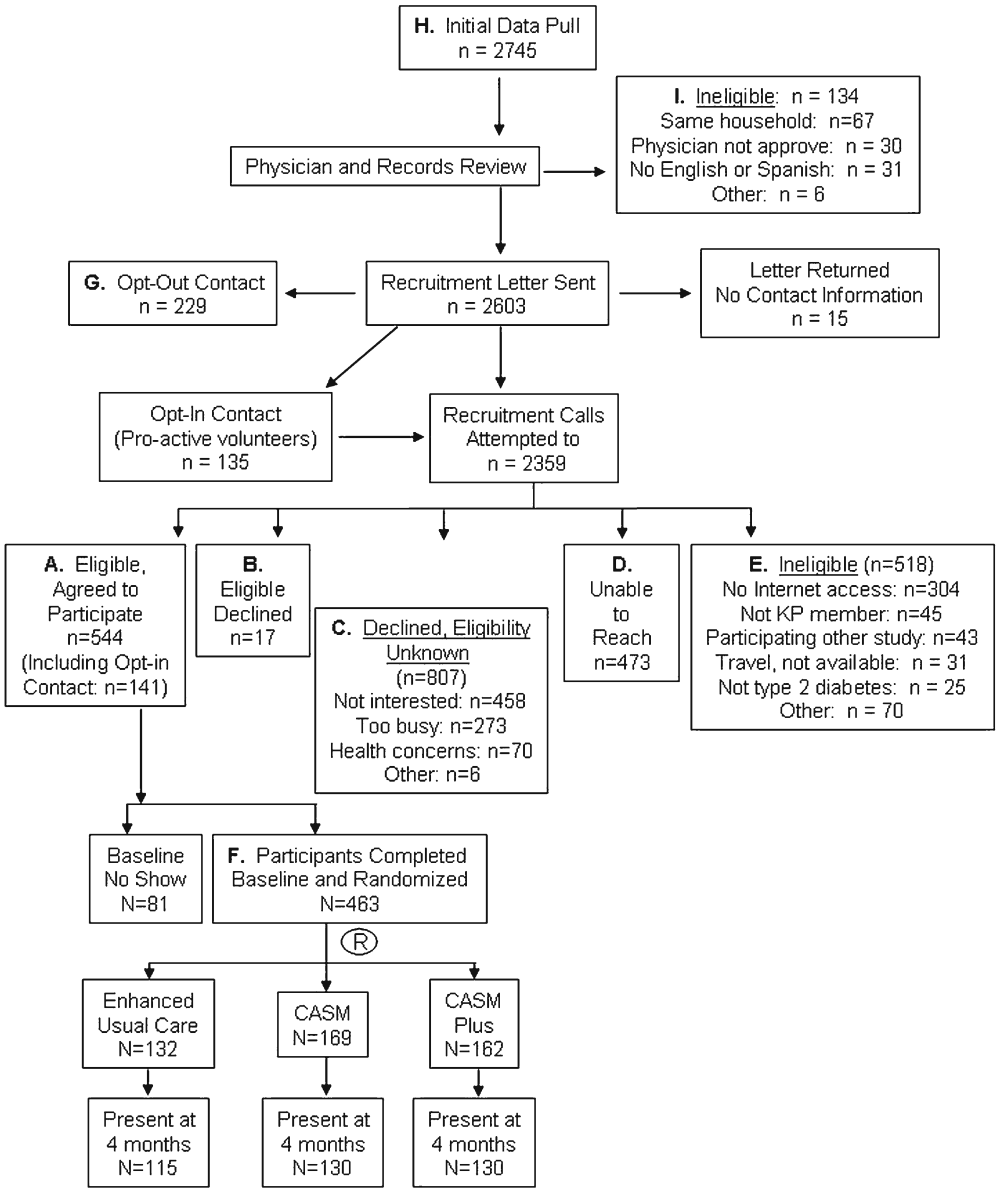

Figure 1. Flow diagram of *My Path/Mi Camino* participation and retention results.

saw participants who preferred Spanish in all conditions. The two extra follow-up calls occurred 2 and 8 weeks after the initial visit to answer any study-related questions and troubleshoot problems with the website or self-management goals, and to discuss the participant's action plans, respectively. The group session focused on healthy eating.

MEASURES

Patient Characteristics. Demographic variables included age, gender, race, Latino ethnicity, household income, and education. Self-efficacy was assessed with Lorig's 8-item Diabetes Self-Efficacy scale.[29] Six additional self-efficacy items, constructed as recommended by Bandura,[30] were added to measure confidence regarding taking diabetes medications, exercising, and limiting high-fat foods. Self-efficacy subscales were calculated for healthy eating, PA, and medication-taking.

Health Literacy and Baseline Computer Use. During the recruitment call, all participants were assessed for health literacy using three items, identified as most sensitive, from the Chew et al literacy instrument.[31] Extent of computer use was assessed by a single question asking how many hours per week on average the respondent spends on a computer.

Behavioral Outcomes. Eating behaviors were assessed using the Ammerman et al[32] "Starting The Conversation" scale, found to be sensitive to change for assessing healthy eating patterns.[33] Starting The Conversation items were averaged to calculate a total score.

Estimated fat intake was assessed using the National Cancer Institute's Percent Energy from Fat Screener.[34] The Community Health Activities Model Program for Seniors (CHAMPS) Questionnaire[35] was used to estimate total weekly caloric expenditure in PA. Adherence to diabetes, blood pressure, and cholesterol medications was assessed through

the medication-taking items of the Hill-Bone Compliance Scale[36] that determines how often and why respondents missed taking medications.

Biological Outcomes. Biologic variables included: body mass index (BMI), hemoglobin A1c, lipids, and mean arterial pressure. Hemoglobin A1c was measured on a Bio-Rad Variant II Turbo liquid by high-pressure liquid chromatography. Lipids were assayed on a modular chemistry analyzer from Roche Diagnostics through a modified version of the Abell Kendal method.

Analyses

Survey data were entered and verified, and descriptive statistics computed to determine the nature of the data and test for assumptions. Chi-square tests and analyses of variance were used to compare baseline characteristics and attrition across conditions. Multivariate analyses of covariance (MANCOVA) were used evaluate outcomes, and controlled for baseline scores on the relevant outcome measures as well as participant characteristics that were significantly related to outcomes at baseline (gender, age, and ethnicity). In addition to statistical significance, we report the effect size *d* (difference in means divided by common standard deviation). Separate analyses were conducted for DSM behaviors (our primary a priori outcomes) as a set, and biological outcomes as a second set. For each set, two a priori planned comparisons were conducted; the first to compare the combined intervention conditions to EUC, and the second to compare the two CASM conditions. When the overall MANCOVA was significant, ANCOVAs were conducted to identify the source(s) of differences. Given the multiple comparisons a $p < 0.01$ level was required for significance. All analyses were conducted using SPSS and NORM.

Missing Data. All analyses were performed two ways. First, a complete-cases approach was used, in which participants with missing follow-up data on the outcome variable were excluded. Second, identical analyses were conducted using multiple imputation procedures for missing data via the expectation-maximization (EM) algorithm with NORM software.[37]

Statistical Power. Power analyses in our grant proposal demonstrated that an initial sample size of 424, allowing for 20% attrition, resulted in a power of 0.90 (alpha = 0.05, two-tailed) to detect an effect size *d* of 0.32 for comparisons between the combined intervention conditions and the EUC condition, and a power of 0.80 to detect a d of 0.28 between the two CASM conditions using the covariance analyses described above. Our observed sample size of 375–463, depending upon measure and time point, exceeded the projected sample size of 339 (424 × 0.08).

RESULTS

Participants and Attrition

A total of 463 patients participated. Recruitment and participant details have been reported elsewhere.[25] We recruited a diverse sample across age, gender, ethnicity (21% Latino), race (14% African American), education and income levels (Table 1). There were no significant differences among conditions on baseline characteristics. Attrition rates (mean of 17.5%) differed by condition (chi-square[2]=6.20, $p = 0.045$); 10.6%

Table 1. Baseline Characteristics of Participants Randomized Across Three Conditions (*n*=463)

Characteristic	All	UC	CASM	CASM+	
	M±SD or %	M±SD or %	M±SD or %	M±SD or %	Sig[1]
		n=132	*n*=169	*n*=162	
Age (Years)	58.4±9.2	58.7±9.1	58.7±9.3	57.8±9.3	0.618
% Female	49.8%	51.5%	44.6%	53.7%	0.231
Race					0.525
American Indian/Alaska Native	6.7%	11.1%	4.9%	4.8%	
Asian	1.6%	1.6%	1.9%	1.4%	
Black or African American	15.4%	12.7%	14.8%	18.4%	
White	72.0%	70.6%	74.1%	70.7%	
Latino ethnicity	21.8%	16.8%	25.3%	25.3%	0.178
Income					0.241
Less than $49,999	47.3%	50.4%	45.7%	46.0%	
$50,000 - $89,999	35.2%	36.6%	33.5%	35.7%	
$90,000 or more	17.5%	13.0%	20.6%	18.2%	
High school or less education	19.1%	13.0%	19.9%	23.6%	0.069
% Low-moderate health literacy	5.9%	7.6%	6.0%	4.3%	0.495
Computer use					0.190
Never to 2½ hrs per week	16.3%	15.1%	16.6%	16.6%	
3 to 6 ½ hours per week	17.7%	21.2%	20.2%	12.4%	
7 to 81/2 hours per week	6.1%	4.5%	5.4%	8.0%	
9 or more hours per week	60.0%	59.1%	57.7%	63.0%	
Smoke cigarettes	10.8%	9.1%	10.1%	13.0%	0.531

[1]*One-way analysis of variance or chi-square test, as appropriate*

attrition in the EUC condition was significantly lower than the 20.8% and 19.8% rates in the CASM and CASM+SS conditions, respectively. Age also differed significantly by attrition status across the three treatment conditions (F (2,451)=3.30, p = 0.038). Those not present at 4 months were younger than continuing participants in the EUC (mean age 57.7 years for dropouts vs. 58.8 participants) and CASM+SS (53.3 vs. 58.9) conditions, but older in the CASM condition (59.4 vs. 58.5). There were no differential attrition effects associated with education, Latino ethnicity, education, gender, smoking status, or computer experience.

Outcomes

Behavior Change. MANCOVA overall results were significant (<0.001) and conclusions were consistent in a priori planned analyses across intent-to-treat and complete-cases analyses comparing combined intervention conditions to EUC (Table 2). Follow-up analyses of individual variables revealed significantly greater improvement for intervention than EUC on three of the four behaviors: eating habits, fat intake, and PA. Secondary treatment-by-participant characteristics interaction analyses, to investigate potential differential effects associated with age, gender, ethnicity, race, education, computer experience, and health literacy, were significant for only one of 28 interactions, suggesting that the intervention effects were generalizable across these factors Table 2).

Comparisons between the two interventions on behavioral improvement were non-significant in both intent-to-treat and complete-cases analyses. If anything, the lower contact CASM condition improved more, albeit non-significantly, on some behaviors.

Biological Outcomes. MANCOVA results failed to reveal significant between-condition differences on biological outcomes (see Table 3). Overall, there were small and modest reductions in BMI, hemoglobin A1c, total/HDL lipid ratio, and blood pressure across conditions, and no indication that CASM+SS produced greater improvements than CASM. Secondary interaction analyses were almost all non-significant and failed to reveal any consistent patterns.

Implementation. Participants were actively engaged in the website, with no differences between CASM and CASM+SS conditions. Detailed implementation data are presented elsewhere.[27] Intervention participants visited the website 27 times on average during the 4-month period.[27] They utilized all aspects of the website, 99% set initial goals for all three targeted behaviors and 81.6% entered self-monitoring data. Usage was consistent across participant characteristics and intervention conditions.

DISCUSSION

Our first goal was to evaluate the feasibility of this intervention using the RE-AIM framework.[19] The program reached a

Table 2. Baseline and 4-month Behavioral Outcomes

	Baseline (M±SD)	4 Months (M±SD)	E.S. (*d*)	Sig. (*p*)
I. Control vs. CASM/CASM+ MANCOVA				
A. Intention to treat (n=444)				
Overall F (4,431)=6.71, p < .001				
Eating habits (total score)				
Control	2.13±0.31	2.19±0.28	0.28	<0.001
CASM/CASM+	2.18±0.30	2.32±0.28		
Fat intake (%)[1]				
Control	35.21±4.70	34.95±4.93	0.26	0.006
CASM/CASM+	34.85±5.12	33.51±5.20		
Physical activity (Cals/Week) [2]				
Control	3979±3292	3241±3221	0.19	0.042
CASM/CASM+	3981±3019	3923±3431		
Medication adherence				
Control	3.78±0.28	3.80±0.37	0.11	0.291
CASM/CASM+	3.77±0.33	3.83±.031		
B. Complete cases (n=338)				
Overall F (4,325)=6.30, p < 0.001				
Eating habits (total score)				
Control	2.15±0.30	2.18±0.26	0.32	<0.001
CASM/CASM+	2.17±0.29	2.31±0.27		
Fat Intake (%)[1]				
Control	34.90±4.73	34.81±4.95	0.28	0.013
CASM/CASM+	34.62±4.96	33.51±4.98		
Physical activity (Cals/Week) [2]				
Control	3885±3306	3098±3107	0.19	0.019
CASM/CASM+	4165±3046	4016±3402		
Medication adherence				
Control	3.77±0.30	3.79±0.39	0.06	0.262
CASM/CASM+	3.80±0.29	3.84±0.29		
II. CASM vs. CASM+ MANCOVA				
A. Intention to treat (n=320)				
Overall F(4,307)=0.80, p = 0.525				
Eating habits (total score)				
CASM	2.19±0.33	2.34±0.31	0.08	0.077
CASM+	2.17±0.26	2.29±0.24		
Fat Intake (%)[1]				
CASM	35.03±5.71	33.48±5.77	0.07	0.458
CASM+	34.67±4.47	33.55±4.58		
Physical activity (Cals/Week) [2]				
CASM	4294±3054	4146±3578	0.08	0.629
CASM+	3664±2959	3697±3272		
Medication adherence				
CASM	3.77±0.34	3.83±0.33	0.03	0.865
CASM+	3.77±.033	3.83±0.29		
B. Intention to treat (n=235)				
Overall F(4,222)=0.82, p = 0.512				
Eating habits (total score)				
CASM	2.17±0.34	2.32±0.30	0.04	0.088
CASM+	2.17±0.25	2.29±0.24		
Fat intake (%)[1]				
CASM	35.23±5.56	33.83±5.54	0.09	0.833
CASM+	34.03±4.26	33.20±4.38		
Physical activity (Cals/Week) [2]				
CASM	4483±3035	4262±3433	0.06	0.672
CASM+	3861±3037	3780±3369		
Medication adherence				
CASM	3.80±0.26	3.83±0.32	0.09	0.690
CASM+	3.80±0.31	3.85±0.25		

NOTE: MANCOVA with eating habits (total score), fat intake (%), physical activity (Calories/Week; CHAMPS), and medication adherence. Baseline outcome scores were covaried. Also covaried were age, gender, ethnicity, and education, which were found in univariate analyses to be related to outcomes at baseline

[1]Outliers were defined as cases reporting >50% calories from fat; to obtain a normal distribution for this variable, outliers were recorded to 50

[2] Calculated from the CHAMPS; values were transformed to obtain normal distribution

Table 3. Baseline and 4-month Biological Outcomes

	Baseline (M±SD)	4 Months (M±SD)	E.S. (*d*)	Sig (*p*)
I. Control vs. CASM/CASM+ MANCOVA				
A. Intention to treat (*n*=444)				
Overall $F(4,431)=0.84$, $p = 0.500$				
Body mass index (kg/m^2)				
Control	34.77±6.55	34.83±6.66	0.13	0.402
CASM/CASM+	34.85±6.54	34.75±6.55		
Hemoglobin A1c (%)				
Control	8.06±1.76	8.00±1.58	0.11	0.145
CASM/CASM+	8.13±1.80	7.95±1.58		
Lipid ratio (Total/HDL)				
Control	3.80±0.98	3.69±0.87	0.00	0.681
CASM/CASM+	4.02±1.18	3.89±1.11		
Mean arterial pressure (mm Hg)				
Control	95.96±11.48	96.64±10.40	0.06	0.994
CASM/CASM+	95.27±10.46	94.42±10.34		
B. Complete cases (*n*=333)				
Overall $F(4,320)=0.62$, $p = 0.645$				
Body mass index (kg/m^2)				
Control	34.75±6.73	34.89±6.84	0.17	0.195
CASM/CASM+	35.35±6.86	35.27±6.86		
Hemoglobin A1c (%)				
Control	7.82±1.54	7.78±1.38	0.05	0.423
CASM/CASM+	7.96±1.54	7.83±1.40		
Lipid ratio (Total/HDL)				
Control	3.77±1.01	3.66±0.88	0.05	0.903
CASM/CASM+	3.87±1.00	3.76±0.95		
Mean arterial pressure (mm Hg)				
Control	95.41±11.94	94.85±10.34	0.05	0.826
CASM/CASM+	94.89±10.40	94.30±10.57		
II. CASM vs. CASM+ MANCOVA				
A. Intention to treat (*n*=320)				
Overall $F(4,307)=0.31$, $p = 0.874$				
Body mass index (kg/m^2)				
CASM	34.47±6.28	34.39±6.27	0.03	0.678
CASM+	35.23±6.78	35.12±6.83		
Hemoglobin A1c (%)				
CASM	8.01±1.85	7.84±1.67	0.06	0.992
CASM+	8.26±1.75	8.05±1.48		
Lipid ratio (Total/HDL)				
CASM	4.00±1.25	3.84±1.16	0.10	0.347
CASM+	4.04±1.11	3.94±1.06		
Mean arterial pressure (mm Hg)				
CASM	95.42±10.40	94.27±10.20	0.05	0.659
CASM+	95.12±10.54	94.58±10.50		
B. Complete cases (*n*=230)				
Overall $F(4,217)=0.17$, $p = 0.955$				
Body mass index (kg/m^2)				
CASM	34.58±6.46	34.54±6.41	0.01	0.540
CASM+	36.15±7.20	36.04±7.25		
Hemoglobin A1c (%)				
CASM	7.86±1.59	7.76±1.50	0.08	0.763
CASM+	8.07±1.49	7.91±1.29		
Lipid ratio (Total/HDL)				
CASM	3.87±1.04	3.74±0.98	0.03	0.865
CASM+	3.90±0.98	3.77±0.93		
Mean arterial pressure (mm Hg)				
CASM	94.48±9.69	93.83±10.27	0.003	0.739
CASM+	95.32±11.13	94.79±10.90		

Note. MANCOVA with body mass index (kg/m^2), Hemoglobin A1c (%), lipid ratio (Total/HDL), and mean arterial pressure (mm Hg). Baseline outcome scores were covaried. Also covaried were age, gender, ethnicity, and education, which were found in univariate analyses to be related to outcomes at baseline.

respectable and fairly representative, conservatively calculated 38% of those contacted and estimated to be eligible (Fig. 1). For an Internet intervention, the 17.5% loss to follow-up was reasonable.[22] Participants in the CASM conditions were actively engaged in using recommended strategies, such as goal setting (almost 100%) and self-monitoring (81.6%). Implementation of the additional support activities among those in the CASM+SS condition was mixed: 88% received at least one additional phone call, but only 38% attended a group visit. Finally, outcomes appear robust across patient characteristics including ethnicity, age, gender, health literacy, education, and prior computer experience.

Our primary goal was to evaluate the effectiveness of *My Path/Mi Camino* on improvement in the DSM behaviors. The intervention conditions improved significantly more than the EUC condition on multiple health behaviors. The effect sizes and magnitude of change were moderate for a minimal-contact condition. The only behavior on which there were not significant effects was medication taking, and this may have been due to either ceiling effects (baseline means of 3.8 on a 4.0 scale) or insensitivity of the self-report adherence measure used. There are not enough studies on the eating behaviors measure to make confident conclusions about magnitude of effects. In general, effect sizes of 0.2–0.3 such as we observed for minimal contact interventions that produce high participation rates[25] are potentially important when multiplied to a population level. To produce public health impact, one needs both moderate to high participation (usually associated with low intensity interventions) and moderate to high effectiveness (typically associated with intensive interventions).[38,39] Given this perspective, a 1% change in estimated fat intake, and behavior change effect sizes of 0.2–0.3 are significant, as a meta-analysis of chronic illness self-management programs found a mean effect size of 0.25.[40]

Differences in behavior did not translate into biological effects, which were secondary outcomes in this study. There was modest improvement in biological outcomes across conditions, but no between-condition differences. Admittedly, other Internet studies have produced larger impacts on biological outcomes,[41,42] but these have been much smaller studies utilizing less stringent comparison conditions. It is still incumbent on us to speculate about how to improve the magnitude of intervention effects. More intensive activities or more time for behavior change may be necessary to result in biological improvements. It is also possible that participants over-reported their behavioral improvements; although, given that the EUC condition also received an interactive computer-based intervention, automated feedback, behavior change recommendations, and the same number of contacts as the CASM condition, there is no reason to expect differential demand across conditions. Although there are epidemiological data linking behavior change to improved health outcomes, the interventions in the present study did not result in improved biological outcomes. From that perspective, the 4-month outcomes would be considered "negative results," and longer-term data on factors such as maintenance of behavior change, health care utilization, and quality of life are needed before drawing conclusions.

The additional support offered to participants in the CASM+SS condition did not lead to enhanced results. More frequent, longer-term, or more personal support may be needed to improve the results of an effective Internet-based behavior-change intervention. Alternative strategies, such as an initial group meeting to introduce participants to the Internet program, may be needed to engage participants in the group activities and peer support.

Limitations of this report include participants from a single health plan (although heterogeneous), self-report measures of behavior change, and the relatively short-term follow-up. Strengths include the large sample with good minority representation, materials in Spanish and English, the randomized practical trial design,[23] the variety of outcomes assessed as recommended for complex interventions, the high levels of engagement and retention for an Internet intervention,[22] and the intent-to-treat analyses. Future research is needed to understand processes that led to these results and potential longer-term effects of the intervention, including impact on patient functioning and cost-effectiveness.

In conclusion, the *My Path/MiCambio* program appears feasible and to produce modest behavior change. In 2009, 74-79% of U.S. adults had Internet access at work or home, and this number is expected to continue increasing. Although there are still disparities in Internet access by age and race/ethnicity, these gaps are decreasing.[43] Sixty-four percent of foreign born Latinos reported Internet access in 2008, compared to 77% of U.S. born Latinos.[44] The present intervention may need to be enhanced via strategies found to increase Internet-based intervention effects in other research such as more personal contact,[9] greater focus on medication taking or stronger linkage to primary care or community resources[15] in order to produce biological or larger behavioral outcomes.

Acknowledgments: *This study was supported by grant #DK35524 from the National Institute of Diabetes and Digestive and Kidney Diseases.*

Conflict of Interest: *None disclosed.*

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REFERENCES

1. **Fisher EB, Brownson CA, O'Toole ML, et al.** Ecological approaches to self-management: The case of diabetes. Am J Public Health. 2005;95:1523–35.
2. **Sallis JF, Owen N, Fisher EB.** Ecological models of health behavior. In: **Glanz K, Rimer BK, Viswanath K, eds.** Health behavior and health education. San Francisco: Jossey-Bass; 2008:465–86.
3. Department of Health and Human Services, Centers for Disease Control and Prevention. National Diabetes Fact Sheet. Available at: http://www.cdc.gov/diabetes/pubs/factsheet07.htm. Accessed 07-22-10.
4. **Deakin T, McShane CE, Cade JE et al.** Group based training for self-management strategies in people with type 2 diabetes mellitus. Cochrane Database Syst Rev. 2005;April 18:CD003417.
5. **Lavizzo-Mourey R, Jung M.** Fighting unequal treatment: The Robert Wood Johnson Foundation and a quality-improvement approach to disparities. Circulation. 2005;111:1208–9.
6. **Glasgow RE, Bull SS, Piette JD, et al.** Interactive behavior change technology: A partial solution to the competing demands of primary care. Am J Prev Med. 2004;27(25):80–7.
7. **Piette J.** Enhancing support via interactive technologies. Curr Diab Rep. 2002;2:160–5.
8. **Bull SS, McKay HG, Gaglio B, et al.** Harnessing the potential of the Internet to promote diabetes self-management: How well are we doing? Chronic Illn. 2005;1(2):143–55.
9. **Tate DF, Jackvony EH, Wing RR.** Effects of Internet behavioral counseling on weight loss in adults at risk for type 2 diabetes: A randomized trial. JAMA. 2003;289(14):1833-1836; PMID 12684363.
10. **Strecher V.** Internet methods for delivering behavioral and health-related interventions (eHealth). Annu Rev Clin Psychol. 2007;3:53–76.
11. **Goldstein MG, Whitlock EP, DePue J.** Multiple health risk behavior interventions in primary care: Summary of research evidence. Am J Prev Med. 2004;27(2 Suppl):61-79; PMID 15275675.
12. **Prochaska JJ, Spring B, Nigg CR.** Multiple health behavior change research: An introduction and overview. Prev Med. 2008;46:181–8.
13. **Peña-Purcell N.** Hispanics' use of Internet health information: An exploratory study. J Med Libr Assoc. 2008;96:101–7.
14. Latino Issues Forum. Latinos, computers and the Internet: How congress and the current administration's framing of the Digital Divide has negatively impacted policy initiatives established to lose the significant technology gap the remains. 2004. Berkeley, Ca.
15. **Leeman-Castillo B, Beaty B, Raghunath S, et al.** LUCHAR: using computer technology to battle heart disease among Latinos. Am J Public Health. 2010;100(2):272–5.
16. **Norris SL, Engelgau MM, Narayan KM.** Effectiveness of self-management training in type 2 diabetes: Systematic review of randomized controlled trials. Diabetes Care. 2001;24(3):561–87.
17. **Glasgow RE, Edwards LL, Whitesides H et al.** Reach and effectiveness of DVD and in-person diabetes self-management education. Chronic Illness. 2009;5:243-249; PMID 19933245.
18. **Thoolen B, de Ridder D, Bensing J et al.** Who participates in diabetes self-management interventions? Issues of recruitment and retention. Diabetes Educ. 2007;May/Jun;33:465-474; PMID 17570877.
19. **Glasgow RE, Linnan LA.** Evaluation of theory-based interventions. In: **Glanz K, Rimer BK, Viswanath K, eds.** Health Behavior and Health Education: Theory, Research, and Practice. San Francisco, CA: Jossey-Bass; 2008:487–508.
20. **Welch G, Shayne R.** Interactive behavioral technologies and diabetes self-management support: Recent research findings from clinical trials. Curr Diab Rep. 2006;6:130-136; PMID 16542624.
21. **Boren SA, Gunlock TL, Krishna S.** et al. Computer-aided diabetes education: A synthesis of randomized controlled trials. AMIA Symposium Proceedings; 2006.
22. **Eysenbach G.** The law of attrition. J Med Internet Res. 2005;7(1):e11; PMID 15829473.
23. **Tunis SR, Stryer DB, Clancey CM.** Practical clinical trials: Increasing the value of clinical research for decision making in clinical and health policy. JAMA. 2003;290:1624-1632; PMID 14506122.
24. **Thorpe KE, Zwarenstein M, Oxman AD, et al.** A pragmatic-explanatory continuum indicator summary (PRECIS): a tool to help trial designers. CMAJ. 2009;180(10):E47–57.
25. **Glasgow RE, Strycker LA, Kurz D et al.** Recruitment for an Internet-based diabetes self-management program: Scientific and ethical implications. Ann Behav Med. 2010;Apr 22 (epub ahead of print). PMID: 20411443.
26. **Glasgow RE, Nutting PA, King DK et al.** A practical randomized trial to improve diabetes care. J Gen Intern Med. 2004;19(12):1167-1174; PMID 15610326.
27. **Glasgow RE, Christiansen S, Kurz D, et al.** Engagement in a diabetes self-management website: Usage patterns and generalizability of program use. J Internet Med Res . 2010. In Press
28. **Nezu AM.** Problem-solving and behavior therapy revisited. Behav Ther. 2004;35:1–33.
29. **Lorig K, Holman H, Sobel Det al.** Living a healthy life with chronic conditions. Palo Alto, CA: Bull Publishing; 2000.
30. **Bandura A.** Self-efficacy: The exercise of control. New York: W.H. Freeman; 1997.
31. **Chew LD, Bradley KA, Boyko EJ.** Brief questions to identify patients with inadequate health literacy. Fam Med. 2004;36(8):588–94.
32. **Ammerman A.** Starting the conversation-diet. Instrument developed by University of North Carolina in conjunction with NC Prevention Partners, and Heart Disease and Stroke Prevention Branch, NC DHHS. 2004. Personal Communication
33. **Fernald DH, Froshang DB, Dickinson LM et al.** Common measures, better outcomes (COMBO): A field test of brief health behavior measures in primary care. Amer J Prev Med. 2008;35(5S):S414-422.
34. **Thompson FE, Kipnis V, Subar AF, et al.** Performance of a short instrument to estimate usual dietary intake of percent calories from fat. Euro J Clin Nutr. 1998;52:S63.

35. **Stewart AL, Mills KM, King AC et al.** CHAMPS physical activity questionnaire for older adults: Outcomes for interventions. Med Sci Sports Exerc. 2001;33(7):1126-1141; PMID 11445760.
36. **Krousel-Wood M, Munter P, Jannu A et al.** Reliability of a medication adherence measure in an outpatient setting. Am J Med Sci. 2005;330:182-133; PMID 16174996.
37. **Schafer JL.** Multivariate normal multiple imputation algorithms. Pennsylvania State University, Department of Statistics University Park. 1994.
38. **Abrams DB, Orleans CT, Niaura RS, et al.** Integrating individual and public health perspectives for treatment of tobacco dependence under managed health care: A combined stepped care and matching model. Ann Behav Med. 1996;18(14):290–304.
39. **Glasgow RE, Nelson CC, Strycker LA et al**. Using RE-AIM metrics to evaluate diabetes self-management support interventions. Am J Prev Med. 2006;30(1):67-73; PMID 16414426.
40. **Weingarten SR, Henning JM, Badamgarav E, et al.** Interventions used in disease management programmes for patients with chronic illness-which ones work? Meta-analysis of published reports. BMJ. 2002;325 (7370):925.
41. **Bond GE, Burr R, Wolf FM, et al.** The effects of a web-based intervention on the physical outcomes associated with diabetes among adults age 60 and older: a randomized trial. Diabetes Technol Ther. 2007;9(1):52–9.
42. **Kim CJ, Kang DH.** Utility of a Web-based intervention for individuals with type 2 diabetes: the impact on physical activity levels and glycemic control. Comput Inform Nurs. 2006;24(6):337–45.
43. Pew Internet Use Reports. Available at: http://www.bing.com/news/search?q=Pew±Internet±Use±Reports&FORM=EWRE&qpvt=Pew±Internet±Use±Reports. Accessed July 22, 2010.
44. Internet World Statistics. Available at: http://www.internetworldstats.com/stats14.htm. Accessed July 22, 2010.