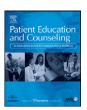
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## Self Management

# Twelve-month outcomes of an Internet-based diabetes self-management support program

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#### ABSTRACT

Objective: Internet-based programs offer potential for practical, cost-effective chronic illness self-management programs.

Methods: We report 12-month results of an Internet-based diabetes self-management program, with and without additional support, compared to enhanced usual care in a 3-arm practical randomized trial. Patients (n = 463) were randomized: 77.3% completed 12-month follow-up. Primary outcomes were changes in health behaviors of healthy eating, physical activity, and medication taking. Secondary outcomes were hemoglobin A1c, body mass index, lipids, blood pressure, and psychosocial factors. Results: Internet conditions improved health behaviors significantly vs. usual care over the 12-month period (d for effect size = .09–.16). All conditions improved moderately on biological and psychosocial outcomes. Latinos, lower literacy, and higher cardiovascular disease risk patients improved as much as other participants.

Conclusions: The Internet intervention meets the reach and feasibility criteria for a potentially broad public health impact. However, 12-month magnitude of effects was small, suggesting that different or more intensive approaches are necessary to support long-term outcomes. Research is needed to understand the linkages between intervention and maintenance processes and downstream outcomes. Practice implications: Automated self-management interventions should be tailored and integrated into primary care; maintenance of patient self-management can be enhanced through links to community resources.

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## 1. Introduction

With the increased prevalence of diabetes [1], there is increasing need for diabetes self-management support that has the ability to reach large numbers of adults [2]. Traditional clinical approaches, such as physician counseling and group-based diabetes education programs [3], have inadequate reach, and have not been sufficient to support long-term behavior changes [4–6]. In addition, primary care offices generally do not have the resources

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or time to provide diabetes self-management education and follow-up support [7,8]. Widespread use of the Internet provides an opportunity to expand the reach of diabetes education programs, and to provide continuous support and tools for achieving necessary changes in multiple lifestyle behaviors, such as healthful eating, regular physical activity, and managing medications [9,10].

Despite reviews suggesting that computerized interactive behavioral health change interventions can be effective [4,11,12], questions remain about whether these programs will prove equitable in terms of access to services, or whether the "digital divide" may increase disparities and about their longer term effects and overall public health impact [13]. From an ecological perspective on health behavior change [14], it is also not known whether website use and outcomes are influenced by factors such as individual characteristics, especially factors such as

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level of computer use and health literacy and numeracy; social network/social support; and community/environmental influences

Evidence from our previous research indicates that effective diabetes self-management interventions (a) incorporate the patient as an active participant in setting goals, (b) are based on behavioral and social-ecological theory, (c) emphasize problem solving and use of supportive resources, and (d) provide proactive follow-up support [15–17]. Translating these important principles into interactive components in an electronic or virtual environment is complex. Furthermore, integrating such programming with primary care activities is important. With the growing emphasis on telemedicine and electronic health records, integrating Internet-based diabetes self-management activities with primary care is a logical step. Whether web-based approaches can eliminate or substantially reduce the need for personal and social support is unclear, and research is needed to understand the right formula of human and computerized support to produce sustained, long-term behavior change [18].

In this paper we follow up on our earlier publications [19,20] to report 12-month results of a three-arm pragmatic randomized trial to evaluate an Internet-based, computer-assisted diabetes self-management (CASM) intervention compared to a CASM plus human support (CASM+) condition. BOTH versions of the intervention were offered in English and Spanish, and compared to enhanced usual care (EUC). Initial results at a 4-month follow-up revealed relatively high levels of website use as well as dietary and exercise behavior improvements relative to the enhanced usual care comparison condition, but only modest and non-significant improvements in biological outcomes relative to the EUC condition [19,20].

Our primary purposes in this article are to expand upon our earlier immediate treatment results to: (a) report longer-term (12-month) results, including engagement, attrition, behavior change, biological impacts, and psychosocial outcomes; (b) using the RE-AIM model, investigate if the earlier, promising engagement and initial behavior change results were maintained and translated into broader public health outcomes at 12 months; and (c) investigate potential effects of moderator variables hypothesized to impact the outcomes of the intervention (e.g., health literacy or numeracy, age, racial or ethnic differences, and level of baseline computer use).

#### 2. Methods

A patient-randomized practical effectiveness trial [21] evaluated two Internet-based diabetes self-management programs relative to EUC. The interventions were (a) self-administered, computer-assisted self-management (CASM), based on social-ecological theory [22] and the "5 As" self-management model [23] and (b) the CASM program with the addition of enhanced social support (CASM+). EUC provided computer-based health risk appraisal feedback and recommended preventive care behaviors using the same contact schedule as the CASM conditions, but did not include the key intervention procedures.

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. [19] and summarized in Fig. 1. Eligibility criteria included: 25–75 years of age, diagnosis of type 2 diabetes, body mass index (BMI) of 25 kg/m² or greater, and at least one other risk factor for heart disease (e.g., hypertension, smoking, hyperlipidemia). 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 ability to perform mild to moderate exercise. Participants were individually randomized via a computer program developed by our computer programmer and statistician. Data were collected from April 2008 to August 2010 and analyzed from September 2010–January 2011. All procedures were approved by the KPCO institutional review board.

#### 2.1. Interventions

Both interventions included a set of behavior change techniques which we have listed using the classification system developed by Michie and colleagues [24]. These techniques are listed in Table 1 by intervention and intervention phase. Social cognitive theory [25] and a social-ecological model [26] were the primary intervention frameworks used. The RE-AIM framework was used for planning and evaluation. Interventions were available in English and Spanish, and based on refinements of interactive self-management programs found effective in our prior research [27].

#### 2.1.1. CASM

CASM participants were given access to the "My Path to Healthy Life" | "Mi Camino A La Vida Sana" website and instructed in log-in, navigation, and usage procedures by a research staff member. Participants were asked to select initial, easily achievable goals in each of three areas: medication adherence, physical activity, and food choices. They recorded their progress on these three daily goals using the tracking section of the website and received immediate feedback on success in meeting their goals over the past 7 days. The website, described in detail elsewhere [28], included a graphic 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 diabetes self-management and healthful lifestyles, as well as features to enhance user engagement, such as rotating quiz questions and motivational tips.

After 6 weeks, participants created personalized "action plans" for medication taking, healthy eating, and physical activity. For each of the three areas, users identified barriers to achieving the goal(s) they had selected, and then chose from a list of problemsolving strategies to overcome those barriers [29]. Each user's action plan summary was available for easy reference and revision. In addition to the website, CASM participants received periodic motivational calls and prompting using a computer-based telephone system that initiated outbound calls, received inbound calls, and collected data.

#### 2.1.2. CASM+

CASM+ participants received all aspects of the CASM intervention with the addition of two follow-up calls from an interventionist, and an invitation to attend three group visits with other participants in the same study condition. The two extra follow-up calls occurred 2 and 8 weeks after the initial visit to answer any intervention-related questions and troubleshoot problems with the website or self-management goals, and to discuss the participant's action plans, respectively. The first call was from a research project staff member and the second call to coordinate with the patients more general diabetes management goals was from a KPCO diabetes care coordinator.

The 120-min group sessions focused on (1) healthy eating, interacting with one's physician and using community resources and (2) maintenance enhancement through the use of analyzing personal behavior chains related to relapse [30]. The first group session for CASM+ participants, scheduled after their action plans were created, focused on healthful eating, and was led by a nutritionist. The meeting included information on healthful restaurant eating behaviors and grocery shopping tips. The second

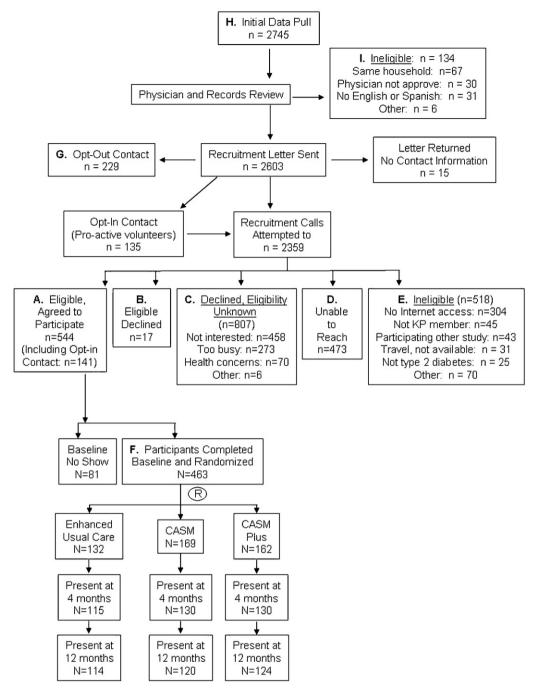


Fig. 1. Flow diagram of My Path/Mi Camino participation and retention results.

group visit was designed to supplement the Behavior Chain exercise introduced to enhance maintenance of the CASM+ intervention. The Behavior Chain Activity was designed to help participants understand that lapses in healthful eating, physical activity, and medication-taking practices usually result from a chain of behaviors leading up to the lapse. The Behavior Chain links may be thought of as high-risk situations in which unhealthful behaviors may be substituted for healthful ones. To prevent future lapses, the activity was designed to help participants identify their links, and then develop strategies for each link in their own Behavior Chain. The third group meeting was led by a bilingual family physician to educate participants about community diabetes resources and how to obtain maximum benefit from their doctor visits.

## 2.2. Measures

Baseline participant characteristics included age, gender, race, ethnicity, income, education level, and tobacco and computer use. Health literacy was assessed during the recruitment call using three items from the widely used assessment of health literacy identified as most sensitive in prior research [31]. Health numeracy was assessed by eight items from the subjective health numeracy scale [32].

## 2.2.1. Behavioral outcomes

Eating behaviors were assessed using the Ammerman et al. [33,34] "Starting The Conversation" scale, found to be sensitive to change for assessing healthy eating patterns [35]. Starting The Conversation items were averaged to calculate a total score.

Table 1
Specific focus on behavior addressing motivation (CASM and CASM+).

Phase of trial	Behavioral technique	Description
First in-person/computer session	Assess health behaviors	Assess levels of dietary fat and FV intake, medication taking, and physical activity (PA), and use the measurement as a motivational tool.
	Assess level of social support	Assess the extent to which friends, relatives, and work colleagues, and more distal sources of support will be supportive of the goal attainment.
	Provide feedback on current behavior	Give feedback arising from assessment of current self-reported or objectively monitored behavior.
	Provide normative information	Give information about how the diet and PA levels compare with national norms
	Use assessment results for tailoring goal setting	Use relevant information from the participant to tailor the behavioral support provided.
	Emphasize choice	Emphasize participant choice within the bounds of evidence-based practice.
	Identify reasons for establishing and maintaining healthful lifestyle	Help the participant to arrive at a clear understanding of health benefits of eating a healthful diet, engaging in regular physical activity, and taking medications.
	behaviors	
	Boost motivation and self- efficacy	Encourage participants to achieve success by setting appropriate goals in small achievable units.
	Facilitate barrier identification	Help participants identify general barriers (e.g., susceptibility to stress) that might make it harder to eat a healthful diet, engage in regular PA, or take medications.
	Facilitate action planning	Work with participants to generate a clear action plan (e.g., days and time of week for engaging in PA).
	Prompt commitment to a healthful lifestyle.	Encourage participants to affirm or reaffirm a strong commitment to start, continue, or restart their goal-attainment efforts.
	Assess self-efficacy (i.e., confidence in success).	Assess confidence in success, and, if low confidence, encourage to reset goals.
	Prompt tracking of lifestyle behaviors.	Help participants establish a routine of recording their daily diet, physical activity, and medication taking to track their own progress toward goals.
Second intervention session and IVR calls	Provide feedback on progress	Give feedback arising from assessment of current self-reported progress toward goal attainment.
	Provide rewards contingent on successful goal attainment	Give praise or other rewards for achieving goals.
CASM+ in-person support group	Facilitate relapse prevention and coping using behavior chains	Help participants understand how lapses occur and how they lead to relapse, and to develop specific strategies for preventing lapses or avoiding lapses turning into relapse.
	Advise on/facilitate use of social support	Advise on or facilitate development of social support from friends, relatives, colleagues, or "buddies."
	Adopt appropriate local community resources	Give information about options for additional support for diet and PA (e.g., websites, self-help groups, telephone helpline).

Estimated fat intake was assessed using the NCI Percent Energy from Fat Screener [36]. The CHAMPS instrument [37] 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 [38] that determines how often and why respondents missed taking medications (with scale scores dichotomized to represent 1 = perfect adherence vs. 0 = other levels of adherence).

## 2.2.2. Psychosocial outcomes

Self-efficacy was measured with Lorig's eight-item Diabetes Self-Efficacy scale [39], which measures participant confidence regarding planning and eating healthful meals, following an eating plan, exercising regularly, and controlling diabetes. Participants rated their confidence on a scale of 1-10, with higher scores indicating greater self-efficacy. Use of problem-solving skills was assessed by six items on the dimension of Positive Transfer of Past Experience from the Diabetes Problem Solving Scale of Hill-Briggs [40]. Supportive resources were measured using nine of the 22 items from the Chronic Illness Resources Survey (CIRS) [41] to assess utilization of social-environmental resources supportive of diabetes self-management. General health status was measured using the visual analog scale from the EuroQol health status instrument, on which participants rate "how good or bad is your own health today?" from 0 (worst) to 100 (best) [42]. The Diabetes Distress Scale (DDS) [43] was used to assess diabetes-related quality of life. This measure assesses the degree to which common diabetes situations are currently problematic for respondents. This was a pragmatic trial [21,44] in a real-world setting and it was not feasible to administer lengthy measurement scales [45]. Selected item subsets and items from these scales were identified based on items that were most strongly associated with the overall scale, and that reflected key subscales (where relevant) a priori thought to be targeted by the intervention, and items that were not considered relevant were deleted (e.g., items on workplace support were deleted since many patients were not employed).

## 2.2.3. Biological outcomes

Biologic variables included: 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 Kendall method.

## 2.3. Analyses

Survey data were entered and verified, and scores were calculated for multiple-item instruments according to previously established procedures. Descriptive statistics were computed to determine the nature of the data and test for normality assumptions. Chi-square tests and analyses of variance were used to evaluate differences in participant characteristics between the treatment conditions, and between dropouts and those who completed the study at 12 months.

## 2.3.1. Moderator analyses

Hierarchical multiple regression models were specified to test for potential effects of variables hypothesized to moderate 4- and 12-month treatment effects. In the first step, the baseline value of the outcome variable and demographic variables (age, gender, computer experience, Latino ethnicity, health literacy, numeracy, education, insulin use, and 10-year coronary heart disease [CHD] risk) were entered. In the second step, treatment condition was entered (1 = EUC; 2 = CASM/CASM+). In the third step, multiplicative interactions between treatment condition and the demographic variables were entered. Because of the large number of moderator analyses, significance was set at p < .01.

## 2.3.2. Generalized estimating equations

Generalized estimating equations (GEE) models [46] were used to compare long-term treatment effects on outcome measures from baseline to 12 months. GEE models were specified using a first-order autoregressive correlation structure, and separate models were conducted to examine treatment group interactions with both linear and quadratic trends. Linear-trend results are presented here, as model results were similar for linear and quadratic trends. Age, gender, Latino ethnicity, and education status (dichotomized at high school) were covaried in all analyses, as they were found in bivariate correlational analyses to be significantly associated with some outcomes at baseline. Separate GEE models were performed to compare the combined intervention conditions to EUC, and to compare the two CASM conditions to each other. Statistical analyses were performed using SPSS 12.0 (SPSS Inc., Chicago). Effect sizes (Cohen's d) were calculated comparing the two treatment conditions on baseline-to-4-month change and on baseline-to-12-month change.

#### 2.3.3. Missing data

GEE analyses were performed two ways. First, a completecase approach was used, in which participants with missing follow-up data on the outcome variable of interest were excluded from the analysis. Second, identical analyses were conducted after missing data were imputed using multiple imputation procedures via the expectation-maximization (EM) algorithm with NORM software [47].

#### 2.3.4. 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 .90 (alpha = .05, two-tailed) to detect an effect size d of .32 for comparisons between the combined intervention conditions and the EUC condition, and a power of .80 to detect a d of .28 between the two CASM conditions on the a priori analyses on primary behavior change outcomes specified in the grant proposal.

#### 3. Results

#### 3.1. Participants and preliminary analyses

A total of 463 patients participated. Recruitment and participant details have been reported elsewhere [19]. We recruited a diverse sample across age, gender, ethnicity (21% Latino), race (14% African American), and education and income levels (Table 2). There were no significant differences among outcomes on baseline characteristics. Distributions of all variables were normal with the exceptions of fat intake and physical activity, which were leptokurtotic. To obtain normal distributions for these variables, cases reporting >50% calories from fat were recoded to 50 and cases reporting >10,000 calories per week of exercise were recoded to 10,000.

Twelve-month attrition rates differed by condition (chi-square = 6.78, p = .034); 18.2% attrition in the EUC condition was significantly lower than the 31.4% and 25.3% rates in the CASM and CASM+ conditions, respectively. Participant characteristics measured at baseline did not differ significantly by 12-month attrition status across the three treatment conditions. Missingness patterns were not found to be systematically related to any of the predictor

**Table 2** Baseline characteristics of participants randomized across three conditions (n = 463).

Characteristic	All M±SD or %	EUC <i>M</i> ± SD or % <i>n</i> = 132	CASM $M \pm SD$ or % $n = 169$	CASM+ $M \pm SD$ or % $n = 162$	Sig <sup>a</sup>
Age (years)	58.4 ± 9.2	$58.7 \pm 9.1$	$58.7 \pm 9.3$	$57.8 \pm 9.3$	.618
% Female	49.8%	51.5%	44.6%	53.7%	.231
Race American Indian/Alaska Native Asian Black or African American White	6.7% 1.6% 15.4%	11.1% 1.6% 12.7%	4.9% 1.9% 14.8% 74.1%	4.8% 1.4% 18.4% 70.7%	.525
	72.0%	70.6%			450
Latino ethnicity	21.8%	16.8%	25.3%	25.3%	.178
Income Less than \$49,999 \$50,000-\$89,999 \$90,000 or more	47.3% 35.2% 17.5%	50.4% 36.6% 13.0%	45.7% 33.5% 20.6%	46.0% 35.7% 18.2%	.241
High school or less education	19.1%	13.0%	19.9%	23.6%	.069
% Low-moderate health literacy	5.9%	7.6%	6.0%	4.3%	.495
Numeracy	$\textbf{4.31} \pm \textbf{1.0}$	$\textbf{4.32} \pm \textbf{0.8}$	$\textbf{4.21} \pm \textbf{1.1}$	$4.39 \pm 1.0$	.720
Computer use Never to 2 h per week 3–6 h per week 7–8 h per week 9 or more hours per week	16.3% 17.7% 6.1% 60.0%	15.1% 21.2% 4.5% 59.1%	16.6% 20.2% 5.4% 57.7%	16.6% 12.4% 8.0% 63.0%	.190
Smoke cigarettes	10.8%	9.1%	10.1%	13.0%	.531

Note: EUC = enhanced usual care control condition; CASM/CASM+ = computer-assisted self-management intervention.

<sup>&</sup>lt;sup>a</sup> One-way analysis of variance or chi-square test, as appropriate.

**Table 3**Number of log-ins to website per month by condition.

Month	CASM condition	CASM+ condition
	Mean (SD); Median	Mean (SD); Median
1	10.45 (9.23); 8	10.86 (9.31); 8
2	7.52 (8.95); 4	7.62 (8.01); 6
3	5.62 (8.14); 2	5.76 (7.15); 3
4	5.12 (8.01); 1	5.24 (6.72); 3
5	5.31 (8.19); 1	5.27 (6.78); 3
6	4.37 (7.31); 1	4.36 (6.12); 2
7	3.75 (7.34); 0	3.77 (5.56); 1
8	3.86 (7.57); 0	3.53 (5.87); 0
9	3.33 (6.79); 0	3.31 (5.80); 0
10	3.49 (7.33); 0	3.22 (5.99); 0
11	3.25 (6.97); 0	2.97 (5.86); 0
12	2.60 (5.76); 0	2.57 (5.22); 0

or outcome variables, suggesting that the data were missing at random and that data-imputation procedures were appropriate.

## 3.2. Moderator analyses

With one exception, none of the hypothesized moderator variables were found in hierarchical multiple regression analyses to significantly affect either 4- or 12-month treatment outcomes. The exception was that Latino ethnicity was a significant moderator of change in blood pressure (only) at 12 months

(*p* = .006), with Latinos reducing blood pressure more than non-Latinos in the CASM/CASM+ conditions while Latinos had less reduction in blood pressure than non-Latinos in the EUC condition.

#### 3.3. Website use

Website use was relatively high initially and throughout the first 4 months. Following the 4-month assessment, as can be seen in Table 3, visits to the website declined considerably from an average of almost 11 times per month in the initial month to an average of fewer than 3 times per month in month 12, with no differences between CASM and CASM+ conditions.

## 3.4. Outcomes

#### 3.4.1. Behavior change

In intention-to-treat (or imputation so titled because imputation analyses model the most likely data for those on whom follow-up data are not complete) analyses, the combined *CASM/CASM+* conditions improved significantly more than the EUC condition over the 12 months of the program in eating habits (condition  $\times$  time chi-square = 9.01, p < .05), fat intake (condition  $\times$  time chi-square = 6.28, p < .05), and physical activity (condition  $\times$  time chi-square = 6.01, p < .05), but not medication adherence (condition  $\times$  time chi-square = 0.49, p > .05) (Table 4). The imputation analyses and complete-cases analyses revealed a highly similar pattern of significant improvement from baseline to 12 months on

**Table 4**Baseline, 4-month, and 12-month behavioral outcomes (estimated means and SEs).

	Baseline $(M \pm SE)$	4 Months $(M \pm SE)$	12 Months $(M \pm SE)$	Condition (chi-square)	Time (chi-square)	$C \times T$ (chi-square)
I. Control vs. CASM/CASM+						
A. Intention to treat						
Eating habits				12.64 <sup>*</sup>	83.06°	9.01°
(score; range = 1/worst – 3/best)						
Control	$2.13 \pm .03$	$2.18\pm.02$	$2.23 \pm .03$			
CASM/CASM+	$2.18\pm.02$	$\textbf{2.31} \pm \textbf{.01}$	$2.32\pm.02$			
Effect size		.32	.15			
Fat intake <sup>a</sup> (%; range = $20-50$ )				3.91 <sup>*</sup>	51.06°	6.28°
Control	$35.18 \pm .40$	$35.11 \pm .41$	$33.91 \pm .37$			
CASM/CASM+	$34.86\pm.28$	$33.71\pm.27$	$33.22 \pm .24$			
Effect size		.24	.09			
Phys activity <sup>b</sup>				1.70	47.93 <sup>*</sup>	6.01°
(Cals/Wk; range = 0-10,000)						
Control	$3915 \pm 294$	$3704 \pm 273$	$2882 \pm 300$			
CASM/CASM+	$3989 \pm 165$	4410 ± 169	$3242 \pm 179$			
Effect size		.23	.09			
Medication adherence dichotomized				0.27	8.80°	0.49
(range = 0/nonadherent – 1/adherent)				0.27	0.00	0.10
Control	$.34\pm.04$	$.38\pm.04$	$.41\pm.04$			
CASM/CASM+	.35 ± .03	$.42 \pm .03$	.43 ± .03			
Effect size		.06	.02			
B. Complete cases		,				
Eating habits				9.33 <sup>*</sup>	71.45°	11.82°
(score; range = 1/worst – 3/best)						
Control	$2.13 \pm .03$	$2.18\pm.03$	$2.24 \pm .03$			
CASM/CASM+	$2.18 \pm .02$	$2.31 \pm .02$	2.31 ± .02			
Effect size		.32	.07			
Fat intake <sup>a</sup> (%; range = 20–50)			,	3.92*	45.12°	4.62°
Control	$35.20 \pm .42$	$35.06 \pm .46$	$33.91 \pm .41$	3.02	10112	1102
CASM/CASM+	$34.84 \pm .29$	$33.69 \pm .30$	$33.04 \pm .29$			
Effect size	3 110 1 ± 120	.22	.12			
Phys activity <sup>b</sup>		.22		2.00	35.37°	5.63°
(Cals/Wk; range = 0–10,000)						
Control	$3953 \pm 302$	$3776 \pm 291$	$2839 \pm 320$			
CASM/CASM+	$4005 \pm 169$	4512 ± 189	$3328 \pm 215$			
Effect size	1000 ± 100	.25	.14			
Medication adherence dichotomized		.20	•••	0.06	9.77*	0.41
(range = 0/nonadherent – 1/adherent)				0.00	0	0111
Control	$.34\pm.04$	$.40\pm.05$	$.44 \pm .05$			
CASM/CASM+	.34 ± .03	.40 ± .03	.41 ± .03			
Effect size	.5.1.05	.00	.06			

Table 4 (Continued)

	Baseline $(M \pm SE)$	4 Months $(M \pm SE)$	12 Months $(M \pm SE)$	Condition (chi-square)	Time (chi-square)	$C \times T$ (chi-square)
II. CASM vs. CASM+						
A. Intention to treat						
Eating habits				3.24 <sup>c</sup>	99.88*	0.78
(score; range = 1/worst – 3/best)				3,2 1	55.65	0.70
CASM	$2.20 \pm .03$	$2.34 \pm .02$	$2.34 \pm .02$			
CASM+	2.17 ± .02	$2.28 \pm .02$	$2.29 \pm .02$			
Effect size	2.17 ± .02	.12	.07			
Fat intake <sup>a</sup> (%; range = 20–50)		.12	.07	0.63	45.54 <sup>*</sup>	0.43
CASM	$34.97 \pm .44$	$33.68 \pm .40$	$33.32 \pm .37$	0.05	45.54	0.45
CASM+	34.76±.36	33.74±.35	33.12 ± .31			
Effect size	34.70±.30	.06	.002			
Phys activity <sup>b</sup>		.00	.002	2.20	44.20	2.16
(Cals/Wk; range = 0–10,000)				2.20	11.20	2.10
CASM	$4302 \pm 233$	$4644 \pm 234$	$3307 \pm 252$			
CASM+	$3662 \pm 230$	$4165 \pm 243$	$3174 \pm 255$			
Effect size	3002 ± 230	.06	.16			
Medication adherence dichotomized		.00	.10	0.40	9.53*	4.25
(range = 0/nonadherent – 1/adherent)				0.40	9.33	4.23
CASM	$.40\pm.04$	$.42\pm.04$	$.43\pm.04$			
CASIVI CASM+	.40±.04	.42 ± .04	.43 ± .04			
Effect size	.30 ±.04	.42 ± .04 .19	.43±.04 .18			
B. Complete cases		.19	.10			
				1.63	88.86 <sup>*</sup>	0.80
Eating habits				1.03	88.86	0.80
(score; range = 1/worst – 3/best) CASM	$2.19 \pm .03$	$2.33 \pm .03$	$2.33\pm.02$			
CASIVI CASM+	$2.19 \pm .03$ $2.17 \pm .02$	$2.33 \pm .03$ $2.29 \pm .02$	$2.33 \pm .02$ $2.29 \pm .02$			
	2.17 ± .02					
Effect size		.08	.07	0.00	20.00*	0.20
Fat intake <sup>a</sup> (%; range = 20–50)	25.00 . 45	22.02 . 47	22.26 . 46	0.88	38.68 <sup>*</sup>	0.36
CASM	35.06 ± .45	$33.82 \pm .47$	$33.36 \pm .46$			
CASM+	$34.62\pm.35$	33.55 ± .39	$32.73 \pm .34$			
Effect size		.04	.05	2.24	20.00*	0.77
Phys activity <sup>b</sup>				2.21	30.06 <sup>*</sup>	0.77
(Cals/Wk; range = $0-10,000$ )						
CASM	$4319\pm241$	$4690\pm266$	$3519\pm305$			
CASM+	$3689\pm233$	$4342\pm269$	$3144\pm301$			
Effect size		.10	.08			
Medication adherence dichotomized				0.58	5.63*	1.48
(range = 0/nonadherent - 1/adherent)						
CASM	$.38\pm.04$	$.41\pm.04$	$.41\pm.05$			
CASM+	$.30\pm.04$	$\textbf{.39} \pm \textbf{.04}$	$.40\pm.04$			
Effect size		.12	.13			

Note: Based on GEE analysis results comparing long-term treatment effects on outcome measures from baseline to 4 and 12 months, and covarying age, education, Latino ethnicity, and gender at baseline, which were found in univariate analyses to be related to outcomes at baseline. DF(condition)=1; DF(time) and DF(condition × time)=2. CASM/CASM+=computer-assisted self-management intervention. Ranges were calculated from the present dataset.

three of the four outcomes, favoring the *CASM* conditions over EUC, with no significant differences between CASM and CASM+ conditions. Effect sizes indicated that the interventions produced strongest gains between baseline and 4 months; improvements in the EUC condition contributed to smaller effect sizes between conditions from 4 to 12 months.

## 3.4.2. Biological outcomes

Participants in the intervention conditions demonstrated consistent, modest improvements on all of the biological outcomes across the 12-month period, but between-condition differences were not statistically significant on any of the measures on imputed or complete-cases analyses (Table 5).

## 3.4.3. Psychosocial outcomes

Intervention participants improved in all psychosocial and quality of life measures across the 12 months, with generally larger effect sizes at 4 months than at the 12 month assessment (Table 6). However, partly due to improvements in the EUC, no significant differential treatment effects were found, with the exception of diabetes distress in complete-cases GEE analysis; the combined

intervention conditions produced greater reductions in distress than the EUC condition (condition  $\times$  time chi-square = 6.26, p < .05).

#### 4. Discussion

The primary purpose of this paper was to investigate the longer-term (12-month) effects of the *My Path* program relative to a relatively stringent enhanced usual care condition. Overall, improvement was seen in most measures, but between-group differences were largely non-significant. The patterns of change varied across outcomes. On the behavioral outcomes, the CASM and CASM+ conditions improved significantly more than the EUC condition across 12 months, but effect sizes indicated that treatment effects were obtained mostly during the first 4 months. On biological outcomes, there were modest improvements across treatment groups, especially on 10-year CHD risk, but no indication that the CASM/CASM+ interventions were superior to EUC. Finally, on the psychosocial variables, there was more variability in outcome patterns, but only one significant difference between conditions across the 12-month period, in reductions in diabetes

<sup>\*</sup> Significant at p < .05 or less.

a Outliers were defined as cases reporting > 50% calories from fat; to obtain a normal distribution for this variable, outliers were recoded to 50.

b Outliers were defined as cases reporting > 10,000 calories per week of exercise; to obtain a normal distribution for this variable, outliers were recoded to 10,000.

c p < .10.

**Table 5**Baseline, 4-month, and 12-month biological outcomes (estimated means and SEs).

	Baseline (M±SE)	4 Months (M±SE)	12 Months ( <i>M</i> ± SE)	Condition (chi-square)	Time (chi-square)	C × T (chi-square)
I. Control vs. CASM/CASM+						
A. Intention to treat						
Body mass (kg/m <sup>2</sup> ; range = 21-61)	249 + 0.0	240 + 0.0	248 + 0.0	0.01	0.73	1.13
Control CASM/CASM+	$34.8 \pm 0.6$ $34.9 \pm 0.4$	$\begin{array}{c} 34.9 \pm 0.6 \\ 34.8 \pm 0.4 \end{array}$	$\begin{array}{c} 34.8 \pm 0.6 \\ 34.6 \pm 0.4 \end{array}$			
Effect size	J4.5 ± 0.4	.17	.12			
Hemoglobin A1c (%; range = 5–16)				0.03	10.54*	1.51
Control	$8.16 \pm 0.16$	$\textbf{8.02} \pm \textbf{0.14}$	$\textbf{8.04} \pm \textbf{0.14}$			
CASM/CASM+	$\textbf{8.14} \pm \textbf{0.10}$	$\boldsymbol{8.00 \pm 0.09}$	$\boldsymbol{8.16 \pm 0.09}$			
Effect size		.00	.11	2.00	10.21*	1 47
Lipid ratio (total/HDL; range=1-11) Control	$3.81 \pm 0.09$	$3.68 \pm 0.0$	$3.77 \pm 0.08$	2.98	10.21°	1.47
CASM/CASM+	$3.81 \pm 0.09$ $3.99 \pm 0.06$	$3.88 \pm 0.06$	$3.88 \pm 0.06$			
Effect size	3.33 ± 0.00	.03	.09			
BP MAP (mm Hg; range = 62-151)				0.19	11.11°	0.73
Control	$\textbf{96.0} \pm \textbf{1.0}$	$94.8 \pm 0.9$	$93.4 \pm 0.9$			
CASM/CASM+	$95.1 \pm 0.6$	$94.4 \pm 0.6$	$93.6 \pm 0.6$			
Effect size		.05	.09	0.54	45.00*	4.50
10-Year CHD risk (%; range=0-50) Control	$8.46 \pm 0.49$	$8.10\pm0.48$	$8.17 \pm 0.48$	0.51	17.20°	1.59
CASM/CASM+	$9.07 \pm 0.38$	$8.41 \pm 0.34$	$8.17 \pm 0.48$ $8.51 \pm 0.38$			
Effect size	3.07 ± 0.50	.12	.09			
B. Complete cases		2	100			
Body mass $(kg/m^2; range = 21-61)$				0.05	0.54	2.49
Control	$\textbf{34.8} \pm \textbf{0.6}$	$34.9 \pm 0.6$	$34.9 \pm 0.6$			
CASM/CASM+	$34.8 \pm 0.4$	$34.7 \pm 0.4$	$34.6 \pm 0.4$			
Effect size		.17	.12		= 0.0*	
Hemoglobin A1c (%; range = 5–16)	0.00 + 0.17	7.00 + 0.14	0.00 + 0.15	0.12	7.36°	0.77
Control CASM/CASM+	$\begin{array}{c} 8.09 \pm 0.17 \\ 8.12 \pm 0.10 \end{array}$	$7.96 \pm 0.14 \\ 7.97 \pm 0.09$	$8.00 \pm 0.15$ $8.12 \pm 0.10$			
Effect size	0.12 ± 0.10	.02	.07			
Lipid ratio (total/HDL; range=1-11)		.02	107	2.17	8.52 <sup>*</sup>	0.65
Control	$\textbf{3.81} \pm \textbf{0.09}$	$3.70\pm0.08$	$\boldsymbol{3.78 \pm 0.09}$			
CASM/CASM+	$\boldsymbol{3.98 \pm 0.06}$	$3.86 \pm 0.06$	$\boldsymbol{3.87 \pm 0.07}$			
Effect size		.02	.11			
BP MAP (mm Hg; range=62-151)	050.10	0.1.0 . 0.0	00.0 . 1.0	0.01	7.16°	1.45
Control	$95.9 \pm 1.0$ $95.2 \pm 0.6$	$\begin{array}{c} 94.6 \pm 0.9 \\ 94.5 \pm 0.6 \end{array}$	$\begin{array}{c} 93.2 \pm 1.0 \\ 94.2 \pm 0.7 \end{array}$			
CASM/CASM+ Effect size	93.2 ± 0.0	.05	.14			
10-Year CHD risk (%; range = 0–50)		.03	.14	0.52	11.02°	0.71
Control	$8.66 \pm 0.54$	$8.26 \pm 0.53$	$\textbf{8.21} \pm \textbf{0.54}$			
CASM/CASM+	$\boldsymbol{9.13 \pm 0.41}$	$\textbf{8.58} \pm \textbf{0.37}$	$\boldsymbol{8.80 \pm 0.42}$			
Effect size		.06	.04			
II. CASM vs. CASM+						
A. Intention to treat						
Body mass (kg/m $^2$ ; range = 21-61)				1.30	3.20	0.10
CASM	$34.4 \pm 0.5$	$34.4 \pm 0.5$	$\textbf{34.2} \pm \textbf{0.5}$			
CASM+	$35.3 \pm 0.5$	$35.2 \pm 0.5$	$35.1 \pm 0.6$			
Effect size Hemoglobin A1c (%; range=5–16)		.04	.00	1.21	15.70°	0.68
CASM	$8.03 \pm 0.14$	$7.89 \pm 0.13$	$8.10\pm0.14$	1.21	15.70	0.08
CASM+	$8.26 \pm 0.13$	$8.10 \pm 0.12$	$8.23 \pm 0.13$			
Effect size		.02	.09			
Lipid ratio (total/HDL; range = 1-11)				1.01	11.87°	1.43
CASM	$\boldsymbol{3.94 \pm 0.09}$	$3.84 \pm 0.09$	$\boldsymbol{3.79 \pm 0.08}$			
CASM+	$\textbf{4.03} \pm \textbf{0.09}$	$3.92 \pm 0.08$	$3.97 \pm 0.10$			
Effect size		.01	.14	0.17	5.50	2.67
BP MAP (mm Hg; range=62-151) CASM	052108	045   09	$92.8 \pm 0.7$	0.17	5.59	2.67
CASM+	$\begin{array}{c} 95.2 \pm 0.8 \\ 95.0 \pm 0.8 \end{array}$	$\begin{array}{c} 94.5 \pm 0.8 \\ 94.3 \pm 0.8 \end{array}$	$92.8 \pm 0.7$ $94.4 \pm 0.9$			
Effect size	33.0 ± 0.0	.00	.15			
10-Year CHD risk (%; range = 0-50)				0.39	27.06°	3.63
CASM	$\boldsymbol{9.43 \pm 0.59}$	$\textbf{8.54} \pm \textbf{0.49}$	$8.66 \pm 0.55$			
CASM+	$\boldsymbol{8.69 \pm 0.48}$	$\textbf{8.28} \pm \textbf{0.46}$	$\textbf{8.35} \pm \textbf{0.51}$			
Effect size		.20	.15			
B. Complete cases				1.01	4.00	0.22
Body mass (kg/m <sup>2</sup> ; range = 21–61) CASM	$34.5\pm0.5$	$34.4\pm0.5$	$34.3 \pm 0.5$	1.01	4.82	0.33
CASM+	$34.5 \pm 0.5$ $35.2 \pm 0.5$	$34.4 \pm 0.5$ $35.1 \pm 0.5$	$34.3 \pm 0.5$ $34.9 \pm 0.6$			
Effect size	33,2 ± 0,3	.00	.05			
Hemoglobin A1c (%; range = 5–16)				1.04	12.90°	2.42
CASM	$\textbf{7.98} \pm \textbf{0.15}$	$\textbf{7.89} \pm \textbf{0.14}$	$\textbf{8.07} \pm \textbf{0.16}$			
CASM+	$8.28 \pm 0.14$	$\textbf{8.05} \pm \textbf{0.14}$	$\textbf{8.18} \pm \textbf{0.14}$			
Effect size		.18	.17			

Table 5 (Continued)

	Baseline (M ± SE)	4 Months (M±SE)	12 Months $(M \pm SE)$	Condition (chi-square)	Time (chi-square)	C × T (chi-square)
Lipid ratio (total/HDL; range=1-11)				0.93	12.08 <sup>*</sup>	0.18
CASM	$3.94 \pm 0.08$	$3.80 \pm 0.08$	$\boldsymbol{3.82 \pm 0.08}$			
CASM+	$\boldsymbol{4.03 \pm 0.09}$	$\boldsymbol{3.92 \pm 0.09}$	$\boldsymbol{3.93 \pm 0.11}$			
Effect size		.05	.03			
BP MAP (mm Hg; range = 62-151)				0.24	2.32	2.34
CASM	$95.4 \pm 0.8$	$94.6 \pm 0.9$	$93.3 \pm 0.9$			
CASM+	$95.1 \pm 0.8$	$94.4 \pm 0.9$	$95.1 \pm 1.1$			
Effect size		.01	.18			
10-Year CHD risk (%; range = 0-50)				0.96	11.89°	3.29
CASM	$9.66 \pm 0.64$	$\textbf{8.81} \pm \textbf{0.53}$	$9.10 \pm 0.60$			
CASM+	$8.57 \pm 0.51$	$\textbf{8.31} \pm \textbf{0.51}$	$\boldsymbol{8.47 \pm 0.58}$			
Effect size		.25	.15			

Note: Based on GEE analysis results comparing long-term treatment effects on outcome measures from baseline to 4 and 12 months, and covarying age, education, Latino ethnicity, and gender at baseline, which were found in univariate analyses to be related to outcomes at baseline. DF(condition)=1; DF(time) and DF(condition × time)=2. CASM/CASM+=computer-assisted self-management intervention. Ranges were calculated from the present dataset.

**Table 6**Baseline, 4-month, and 12-month psychosocial and quality of life outcomes (estimated means and SEs).

	Baseline $(M \pm SE)$	4 Months $(M \pm SE)$	12 Months $(M \pm SE)$	Condition (chi-square)	Time (chi-square)	C × T (chi-square)
I. Control vs. CASM/CASM+						
A. Intention to treat						
Self-efficacy				3.25 <sup>a</sup>	6.00°	3.70
(score; range = 1/low efficacy – 14/high						
efficacy)						
Control	$6.90\pm.14$	$6.69\pm.15$	$6.91\pm.16$			
CASM/CASM+	$\textbf{7.02} \pm .10$	$7.09\pm.09$	$\textbf{7.22} \pm .09$			
Effect size		.19	.13			
Problem solving				2.35	54.53 <sup>*</sup>	2.61
(score; range = $1/low skill - 5/high skill$ )						
Control	$2.95\pm.06$	$\textbf{3.03} \pm \textbf{.06}$	$3.18\pm.06$			
CASM/CASM+	$2.99 \pm .04$	$3.17\pm.04$	$3.29\pm.04$			
Effect size		.16	.10			
Supportive resources (score; range = 1/low				2.37	4.76 <sup>a</sup>	1.37
support – 5/high support)						
Control	$1.91\pm.05$	$\boldsymbol{1.93 \pm .06}$	$1.94\pm.06$			
CASM/CASM+	$1.97\pm.04$	$2.05\pm.04$	$\textbf{2.04} \pm \textbf{.04}$			
Effect size		.12	.08			
General health state (score; range = 10/poor				0.00	13.80°	0.45
health – 100/excellent health)						
Control	$68.7 \pm 1.4$	$71.7\pm1.3$	$71.1 \pm 1.4$			
CASM/CASM+	$69.0 \pm 1.0$	$71.7 \pm 0.9$	$\textbf{70.5} \pm \textbf{1.0}$			
Effect size		.02	.06			
Diabetes distress (score; range = 1/low				0.17	46.91*	5.47 <sup>a</sup>
distress – 6/high distress)						
Control	$3.00 \pm .11$	$2.87\pm.10$	$2.72\pm.10$			
CASM/CASM+	$3.08 \pm .07$	$2.71 \pm .06$	$2.66 \pm .06$			
Effect size	3,00 ± 107	.23	.14			
B. Complete cases		.23	***			
Self-efficacy (score; range = 1/low				2.16	5.87	4.51 <sup>a</sup>
efficacy – 14/high efficacy)				2.10	5.07	1.51
Control	$6.94 \pm .15$	$6.69 \pm .17$	$6.97 \pm .18$			
CASM/CASM+	$7.00 \pm .10$	$7.10 \pm .10$	$7.22 \pm .10$			
Effect size	7.00 ± .10	.24	.13			
Problem solving (score; range = 1/low		.24	.15	1.08	43.39 <sup>*</sup>	3.64
skill – 5/high skill)				1.00	45.55	5.04
Control	$2.98\pm.07$	$3.04\pm.07$	$3.21\pm.06$			
CASM/CASM+	$2.99 \pm .04$	$3.19 \pm .04$	$3.26 \pm .04$			
Effect size	2.33 ± .04	.23	.06			
Supportive resources (score; range = 1/low		.23	.00	2.94ª	4.05	3.66
support – 5/high support)				2.54	4,05	5.00
Control	$1.93\pm.06$	$1.92\pm.06$	$1.94\pm.06$			
CASM/CASM+	$1.97 \pm .03$	$2.05 \pm .04$	$2.08 \pm .04$			
Effect size	1.57 ± .05	.18	.20			
General health state (score; range=10/poor		.10	.20	0.17	46.91*	5.47a
health – 100/excellent health)				0.17	40. <i>3</i> i	J. <del>T</del> /
Control	$68.5 \pm 1.5$	$\textbf{70.8} \pm \textbf{1.5}$	$70.9 \pm 1.5$			
CASM/CASM+	$68.5 \pm 1.5$ $69.0 \pm 1.0$	$70.8 \pm 1.5$ $71.4 \pm 1.0$	$70.9 \pm 1.5$ $70.5 \pm 1.1$			
Effect size	U3.U ± 1.U	/1.4 ± 1.0 .01	$70.5 \pm 1.1$ .06			
		.01	.OO.	0.01	42.54*	6.26*
Diabetes Distress (Score; range = 1/low				0.01	42.54	6.26
distress – 6/high distress)	2.00 + 11	2.05   11	2.62 + 11			
Control	$2.96\pm.11$	$2.85\pm.11$	$2.63\pm.11$			

Significant at p < .05 or less.

Table 6 (Continued)

	Baseline $(M \pm SE)$	4 Months $(M \pm SE)$	12 Months $(M \pm SE)$	Condition (chi-square)	Time (chi-square)	$C \times T$ (chi-square)
CASM/CASM+	$3.07\pm.07$	2.69 ± .07	2.64±.07			
Effect size		.26	.10			
II. CASM vs. CASM+						
A. Intention to treat						
Self-efficacy (score; range = 1/low				7.92 <sup>*</sup>	7.01°	$4.70^{a}$
efficacy – 14/high efficacy)						
CASM	$7.35\pm.15$	$7.25\pm.12$	$\textbf{7.41} \pm \textbf{.11}$			
CASM+	$6.68\pm.14$	$6.93\pm.13$	$\textbf{7.02} \pm .13$			
Effect size		.24	.19			
Problem solving (score; range = 1/low				2.49	59.04°	3.00
skill – 5/high skill)						
CASM	$\boldsymbol{3.08 \pm .06}$	$3.22\pm.05$	$\textbf{3.31} \pm .05$			
CASM+	$2.90\pm.06$	$3.12\pm.06$	$3.26\pm.06$			
Effect size		.13	.19			
Supportive resources (score; range = 1/low				2.19	8.69°	2.51
support – 5/high support)						
CASM	$2.05\pm.05$	$2.09 \pm .05$	$2.07\pm.06$			
CASM+	$1.90\pm.04$	$2.01\pm.05$	$2.01\pm.05$			
Effect size		.14	.18			
General health state (score; range = 10/poor				4.97 <sup>*</sup>	8.89°	0.72
health – 100/excellent health						
CASM	$70.8 \pm 1.3$	$73.9 \pm 1.2$	$71.9 \pm 1.3$			
CASM+	$67.1 \pm 1.5$	$69.5 \pm 1.4$	$69.0\pm1.5$			
Effect size		.04	.05			
Diabetes distress (score; range = 1/low				7.16 <sup>*</sup>	67.25°	2.93
distress – 6/high distress)						
CASM	$2.88 \pm .10$	$2.58\pm.09$	$2.55\pm.08$			
CASM+	3.29 ± .10	$2.84 \pm .09$	$2.78 \pm .09$			
Effect size		.15	.18			
B. Complete cases						
Self-efficacy (score; range = 1/low				10.20°	5.60 <sup>a</sup>	1.22
efficacy – 14/high efficacy)						
CASM	$7.33 \pm .15$	$7.33 \pm .14$	$7.49 \pm .13$			
CASM+	$6.68 \pm .14$	$6.88 \pm .14$	$6.97 \pm .14$			
Effect size		.14	.09			
Problem solving (score; range = 1/low			.00	1.62	44.19°	4.41
skill – 5/high skill)				1102		
CASM	$\textbf{3.07} \pm .06$	$3.25\pm.06$	$3.25\pm.06$			
CASM+	$2.92 \pm .06$	$3.12 \pm .06$	$3.26 \pm .06$			
Effect size	2102 ± 100	.03	.24			
Supportive resources (score; range = 1/low		.03		2.45	10.65°	1.31
support-5/high support)				21.15	10.00	
CASM	$2.04\pm.05$	$2.10\pm.05$	$2.11 \pm .06$			
CASM+	$1.90 \pm .04$	$2.00 \pm .05$	$2.05 \pm .06$			
Effect size	1.50 ± .01	.08	.16			
General health state (score; range = 10/poor		.00	.10	4.09°	6.49°	1.41
health – 100/excellent health)				1.00	0.15	1.11
CASM	$70.6 \pm 1.3$	$73.8 \pm 1.3$	$71.7 \pm 1.6$			
CASM+	$67.3 \pm 1.5$	$69.0 \pm 1.6$	$69.2 \pm 1.6$			
Effect size	U1.J I I.J	.09	.05			
Diabetes distress (score; range=1/low		.03	.03	5.88 <sup>*</sup>	58.23°	1.97
distress – 6/high distress)				3.00	JU.2J	1.37
CASM	$2.88\pm.10$	$2.59\pm.10$	$2.49\pm.09$			
CASM+	$3.27 \pm .10$	$2.39 \pm .10$ $2.79 \pm .10$	$2.49 \pm .09$ $2.78 \pm .10$			
Effect size	J.4/ I.10	2.79±.10 .18	2.78 ± .10 .10			

Note: Based on GEE analysis results comparing long-term treatment effects on outcome measures from baseline to 4 and 12 months, and covarying age, education, Latino ethnicity, and gender at baseline, which were found in univariate analyses to be related to outcomes at baseline. DF(condition)=1; DF(time) and DF(condition × time)=2. CASM/CASM+=computer-assisted self-management intervention. Ranges were calculated from the present dataset.

distress. These patterns were similar across both complete-cases and intent-to-treat imputation analyses. In no analysis did the CASM+ condition improve significantly more than the CASM condition, a largely self-administered web-based intervention.

The general lack of treatment effects, with the exception of behavioral outcomes and diabetes distress, suggests that it is difficult to improve upon reasonably good "enhanced usual care" that included regular assessments, personalized (albeit computer-facilitated) attention, periodic feedback on health behaviors, and access to health plan and community resources in the context of an organized care system that had prioritized diabetes care. It

may be that a considerably more intensive (and costly) intervention, such as in the DPP [48], is required to improve upon this basic set of supportive conditions to produce generalizable effects that produce improvement beyond these components and extraneous factors. The website use data support this interpretation as they demonstrate decreasing website usage over time, despite the addition of the modest additional contacts in the CASM+condition.

It is also possible that our decision to select heterogeneous patients, to be more similar to those seen in practice, rather than only those needing in improvement on our primary health

<sup>\*</sup> Significant at p < .05 or less.

a p < (or =) .10.

behavior outcomes or on HbA1c, along with attrition limited our ability to detect intervention effects.

However, as Schillinger and colleagues demonstrated [2], an increase in the frequency of interactive technology-based strategies linked to nurse care management (i.e., weekly automated telephone self-management sessions over 9 months) CAN result in moderate effect sizes across indicators of patient perceptions of their care, quality of life, and behavioral self-management skills. Further, the automated telephone self-management intervention in their study was superior to monthly group medical visits across a number of behavioral outcomes. These findings, coupled with our own, suggest that investigation into the necessary frequency and duration of interactive technology interventions like CASM, and the optimal and most cost-effective balance between human- and computer-delivered content, remains a ripe area for future research [17,18].

It was encouraging that relapse between the 4- and 12-month assessments was modest, despite no in-person contact between these assessments. When combined with the results of a parallel randomized study, comparing in-person brief diabetes selfmanagement education to a mailed DVD intervention with different but highly similar type 2 diabetes patients from this same health plan [49], we conclude that automated and computerassisted interventions are appealing to diabetes patients, offer a number of advantages in terms of accessibility and convenience, and can produce improvements in behavioral, biologic, quality of life, and psychosocial outcomes. For many patients, however, a more intensive, longer, or a substantially different type of intervention may be required to produce improvements in biological outcomes beyond this basic level. Our results also suggest that different or more extensive intervention approaches may be necessary to support long-term changes in multiple health

An intriguing result was the consistent pattern of results from the moderator analyses. There was only one significant interaction (Latino ethnicity  $\times$  treatment condition) in predicting an outcome (blood pressure). We conclude that the intervention worked equally well among Latinos (possibly better for blood pressure reduction), lower health literacy and numeracy patients, those at higher risk of coronary heart disease, and those with varying levels of computer experience (as well as other variables).

This report has both strengths and limitations. Strengths are the high patient participation rate relative to other reports of diabetes self-management [19,49], the pragmatic RCT design [21,44] and multiple measures of hypothesized theory-based intervention processes; the availability of the intervention in both English and Spanish; use of a priori comparisons and use of GEE and imputation analyses for missing data. The reasonably large and moderately diverse sample size also permitted investigation of moderator effects, although inclusion of a wider range of patients from multiple settings and an even larger sample would have provided more power for moderation analyses.

Limitations are the restriction to one health maintenance organization (but five different clinics and a moderately diverse sample), that the significant effects were restricted to self-report measures, and moderate but differential attrition (similar to other Internet interventions [11,12,44]. The greatest limitation of the CASM intervention, as discussed in greater detail in separate mixed-methods manuscripts [50,51], is that the program was not highly integrated with the patient's primary health care. Despite considerable efforts and the existence of a state-of-the-art electronic health record, we were unable to integrate progress reports, goals, or other findings from the CASM program into these electronic records in an optimal way to primary care providers so that the information was prominently available to patients and clinicians at the time of their visits.

## 4.1. Practical implications

Website developers, program implementers, and future research should explore whether a computer-tailored self-management intervention that is part of the patient health record, delivered through a patient personal health record portal, with patient goals and progress more visible to providers would produce stronger results than the present intervention. An important direction for future research and practice is to identify ways to strengthen the sustainability of the Internet intervention without adversely impacting its reach or substantially increasing costs [52]. Such approaches might include innovations to more strongly integrate the intervention with primary care or to make the intervention more mobile and available to participants throughout their day [53]. Additional evaluations are also needed to evaluate cost-effectiveness, and to understand the linkages between intervention and maintenance processes and outcomes.

#### **Conflict of interest**

All authors declare no conflicts of interest.

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