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Diabetes Technology & Therapeutics

ORIGINAL ARTICLE

A Randomized Comparison of Online- and Telephone-Based Care Management with Internet Training Alone in Adult Patients with Poorly Controlled Type 2 Diabetes

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Abstract

Aims: Care management may improve the quality of diabetes care by enhancing contact between high-risk patients and their providers. This prospective, longitudinal, randomized trial sought to investigate whether telephone or online care management improves diabetes-related outcomes over time compared with usual care supplemented with Internet access and training.
Subjects and Methods: One hundred fifty-one adult subjects with type 2 diabetes mellitus and an elevated hemoglobin A1c (A1c) level ($\geq 8.5\%$) were randomly assigned to online care management ($n = 51$), telephone-based care management ($n = 51$), or Web training ($n = 49$) groups. Online and telephone participants interacted with a care manager through a diabetes education and care management Web site and by telephone, respectively. The Web training group was provided with online diabetes self-management resources but no care management support. The primary outcome measure was A1c measured every 3 months for a year.
Results: A1c declined significantly and substantially in all groups over 12 months. A1c declined linearly at a rate of 0.32% ($P < 0.0001$) per quarter for the online group, 0.36% ($P < 0.0001$) for the telephone group, and 0.41% for the Web training group ($P < 0.0001$). The rate of change over time did not differ significantly among groups. The groups converged at 12 months with average absolute A1c difference of -1.5%. The number of interactions with care providers was not significantly associated with the change in A1c. Blood pressure, weight, lipid levels, and diabetes distress did not differ among groups over time.
Conclusions: Online, telephone-based care management, and Web training for diabetes patients with elevated A1c were each associated with a substantial improvement in A1c over a 1-year period. Internet access and training alone may be as effective as care management in patients with poorly controlled diabetes.

Introduction

DIABETES IS A MAJOR COMPONENT of healthcare expenditures in the United States.[1,2] Poor control of glucose, blood pressure, and lipids in patients with diabetes is associated with substantially increased healthcare utilization and cost. In an attempt to address these high-risk, high-cost patients, many healthcare systems have employed care management programs and have engaged nurses or other allied health professionals (e.g., pharmacists, nutritionists) as the point of contact for patients.

As with most chronic diseases, the vast majority of diabetes-related self-care and activity occurs outside the healthcare setting. Nevertheless, traditional models of patient education and care management require that encounters between care managers and patients occur at times convenient for both individuals. Scheduling and travel are potential barriers to completing these connections. Online tools could potentially neutralize geographic and scheduling barriers.[3] Patients and providers are increasingly using online platforms to communicate and learn. Online care allows patients to retain a relationship with their primary care provider between visits and can reinforce and track the assigned goals for each patient by facilitating communication and data transfer. We previously demonstrated that online care management can be a useful adjunct in the care of patients with poorly controlled diabetes and can improve the attainment of diabetes goals.[4] Nevertheless, few studies have compared the efficacy of different implementation strategies on clinical outcomes in patients with diabetes.

Even in the most successful trials of diabetes care management, many participants do not attend or participate in all sessions. Thus, it is useful to examine the range of different models for effectively engaging patients in their care.[5] Some care management programs have demonstrated significant system-wide cost savings despite increased costs in the subcategories of pharmacy and care management administration, but others have not.[6–9] Randomized and nonrandomized interventions have shown some efficacy in lowering hemoglobin A1c (A1c), but there are limited data on the efficacy of care management for individual patients.[10–17] Consequently the benefits of care management approaches have been questioned. This is particularly relevant as self-management information has become increasingly ubiquitous online where communities of patients can engage in reinforcing group interactions while tracking a range of health outcomes.[5,10,18]

In this study we examined the efficacy of two methods of diabetes education and care management for patients with particularly poorly controlled diabetes: a traditional model that involved face-to-face encounters and telephone contact and an online model that facilitated asynchronous online communication and data sharing. We compared these interventions with an Internet access and training ("Web training") group that was directed to a series of diabetes self-management Web sites. We tested the hypotheses that active care management in patients with elevated A1c levels ($\geq 8.5\%$) using traditional or online methods would (1) reduce A1c levels, (2) improve cardiovascular risk factors, and (3) reduce diabetes-related distress when compared with usual care supplemented with Web training over a 12-month period.

Subjects and Methods

Study protocol

The study was conducted at the Department of Veterans Affairs (VA) Boston Healthcare System. The protocol was reviewed and approved by the Institutional Review Board, and informed, written consent was obtained from each participant. Eligibility criteria included A1c level $> 8.5\%$, age > 25 years, ability to understand written and spoken English, access to a telephone, and willingness to use a notebook computer and glucose and blood pressure monitoring devices. Participants were required to have a VA-based primary care provider at one of four hospital-based clinics or 10 community-based outpatient clinics.

For recruitment, hospital laboratory data were screened monthly to identify individuals age > 25 years and with a recent A1c level encompassing or within 0.5% of the A1c inclusion criterion. Potential participants were sent a letter and/or brochure describing the study, and follow-up telephone calls were attempted at least 2 weeks later to solicit participation. Following in-person screening, eligible participants attended an additional information session to review the study design. Participants were then randomized to one of three study groups through the use of a random number generator and a series of sealed envelopes. Those assigned to the groups afforded computer use received in-person orientation and training.

Telephone-based care management group.   Participants randomized to telephone-based care management were given monitoring devices for glucose (AccuChek® Advantage;

Roche Diagnostics, Indianapolis, IN) and blood pressure measurements (Omron Medical, North Bend, WA). An advanced practice nurse or clinical pharmacist met with each patient and used a care management intervention and follow-up schedule based on a previously published report.[19] Both care managers were Certified Diabetes Educators and between them had 30 years of experience in care management.

Participants assigned to this group met with the care manager for an initial assessment to review glucose and blood pressure monitoring techniques and schedules and received instruction in the core content areas suggested by the American Diabetes Association.[20] Care managers used integrated case management software to log and track results (CDMP; Estenda Solutions, Conshohocken, PA). Interim follow-up telephone calls occurred approximately biweekly during which the care manager reviewed the home glucose and blood pressure readings with the participant. These care manager–participant contacts were used to review progress, reinforce nutritional and lifestyle modifications, and make medication changes using the treatment algorithms that were developed from and were consistent with the standards of the American Diabetes Association.[20] Medications were adjusted by the care managers and affirmed by the participant's primary care provider, who then implemented the medication changes through the hospital pharmacy.

Online care management group.   Participants randomized to online care management received a notebook computer and Internet access, if needed, and the same glucose and blood pressure monitors provided to the telephone-based care management group. Subjects also met with one of the two care managers and were encouraged to perform blood pressure monitoring at least three times weekly; recommendations for glucose testing were individualized for each patient. Participants in this study arm were asked to log-in to the patient portal of an Internet-based care management application at least biweekly. The care management application had a provider portal that allowed the care managers to review a patient panel, assign educational modules covering medications, nutrition, exercise, glucose monitoring, and well-being, review uploaded glucose and blood pressure monitoring data, and communicate securely with the patient via an internal messaging system. The program provided interpretations of the participant's progress using a combination of biochemical data downloaded from the hospital laboratory and process indicators (including vaccinations and foot and dilated eye examinations during the preceding 12 months) provided by the clinician. The care manager used the same medication algorithms as in the telephone-based care management arm and communicated with primary care providers regarding medication changes. Contact with patients was primarily through the sending and receiving of messages via the Web site or, if necessary, through telephone contact. We provided telephone reminders to participants who had not logged into the website within 2 weeks to encourage Web site usage.

Usual care supplemented with Internet access and online self-management resources ("Web training").   Participants randomized to the Web training group were provided with a laptop computer and Internet access with training in the use of the device as necessary. The home page of the computer's

Internet browser was set to a diabetes education Web site designed for the study, containing links to several Web sites with vetted content related to diabetes self-management including sites that facilitated peer-sharing and mutual support. Utilization of these resources was at the private discretion of the patient, and study staff had contact with these participants only to arrange and conduct follow-up visits for the collection of outcome measures.

For all three groups, the follow-up visits occurred every 3 months. Regardless of study group, all participants continued with ongoing care from their primary care provider as determined by their clinical needs.

Outcome measures. The primary outcome measures were change in A1c and blood pressure over time. These outcome measures were collected at baseline and 3, 6, 9, and 12 months after randomization. A1c was measured with methodology that utilized a nonporous ion-exchange high-performance liquid chromatography to separate A1c from other hemoglobin fractions and is certified by the National Glycohemoglobin Standardization Program. Blood pressure was measured with the patient in the seated position after a 5-min rest using an appropriately sized cuff and an automated sphygmomanometer. Three readings were taken 1 min apart, and analyses used the average of these three readings. Fasting serum samples were assayed for cholesterol, its subfractions, and triglycerides using standard laboratory techniques. We analyzed lipid profiles obtained at baseline and 12 months. The patients' primary care providers were generally masked to clinical outcome measures unless they requested access to specific test results to avoid duplicate laboratory testing.

Diabetes distress was measured at baseline and 12 months using the Problem Areas in Diabetes (PAID) questionnaire.[21,22] The PAID comprises 20 items, incorporating questions regarding feelings of guilt, anxiety, worry, loneliness, and burnout from diabetes, feelings about diabetes care providers, and level of comfort with social situations, among other things. Each item is coded to indicate the severity of a problem ($0 =$ not a problem to $4 =$ serious problem), and the total score for the instrument varies from 0 to 100.

Data on process measures (including number of Web site interactions, number of encounters, and time spent by the care managers per patient encounter) and changes in diabetes and antihypertensive medications were collected every 3 months and analyzed as possible explanations for interindividual differences in change over time in the primary outcomes. Medications prescribed for glucose, lipid, and blood pressure control were tracked at each visit, and clinic and emergency room visits were counted.

Statistical analyses

The goal of the analyses was to compare outcome measures among the telephone-based care management group, the online care management group, and the Web training group. For participants who missed study visits or did not respond to
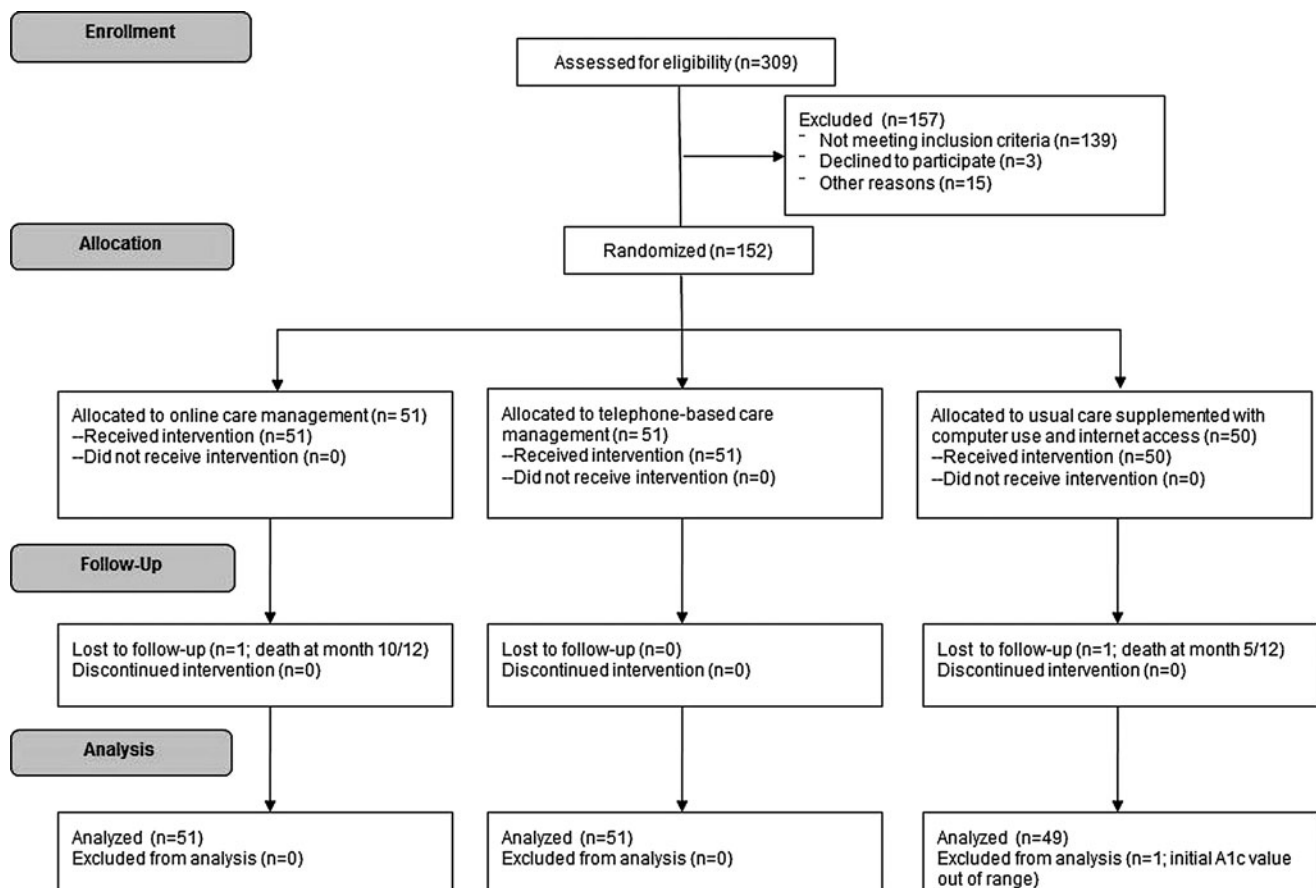

FIG. 1. Flow of patients through the study. A1c, hemoglobin A1c.

all questions, the study carried forward the last or most recent observations. However, if subjects were missing data at baseline, as was the case for several subjects who were missing baseline lipid values, we did not carry forward observations. We minimized missing data by including A1c data from the medical record for patients who missed follow-up visits but had lab tests within the required time frame for the study protocol.

The analyses first compared the study participants' baseline characteristics using one-way analysis of variance for continuous variables and χ^2 tests for qualitative variables. The analyses then compared baseline and 12-month values for the outcomes—within each study group—using paired t tests. Lastly, the analyses examined trajectories of the groups' outcome measures using multilevel models for longitudinal data (PROC MIXED, SAS version 9.2; SAS Institute, Cary, NC). These models included time effects and the interaction of time effects with treatment group to detect within-individual differences as well as differences in the rate of change in the outcomes between the groups over the course of the study. As needed, the analyses included baseline characteristics, usage of the care management portal, and contacts with care managers. All analyses were "intent-to-treat."

Results

The study enrolled 151 participants (Fig. 1). Table 1 shows baseline characteristics of the study participants according to randomization group. Participants had a mean age of 60

years, 95% were male, 90% had completed a high school education, and 49% had a diabetes diagnosis for >10 years. In the online care, telephone care, and Web training groups, 47, 44, and 41 subjects completed the trial, respectively. Computer training and support were provided for a mean total of 122.4 min (range, 0–256 min) per subject in the Web training and online care groups.

Baseline A1c levels for participants in the online care management, telephone-based care management, and Web training groups were 9.5%, 9.8%, and 10.0%, respectively. As shown in Table 2, there was a marked and significant decrease in A1c in all study groups over the 12-month period with most of the change occurring within the first 6 months (Fig. 2). Also, from the multilevel models, A1c declined linearly from baseline at a rate of 0.32% per 3-month interval for the online group ($P < 0.0001$ for the null hypothesis of no change from baseline), 0.36% ($P < 0.0001$) for the telephone group, and 0.41% for the Web training group. The rate of change over time did not differ significantly between groups ($P = 0.12$ for the online care group compared with the Web training group and $P = 0.35$ for the telephone care group compared with the Web training group), suggesting no significant intervention effects. The groups converged at the end point with average A1c between 8.3% and 8.4% after 12 months in the trial.

We also examined A1c responses in the 54 (36%) patients with markedly elevated A1c levels ($\geq 10\%$). Again, all study groups had similar results, with significant ($P < 0.001$) declines in A1c (-2.4% to -2.6%) but no between-group differences.

TABLE 1. BASELINE CHARACTERISTICS

Parameter	Total (n=151)	Web training (n=49)	Telephone care (n=51)	Online care (n=51)	P[a]
Age (years) [mean (SD)]	60.2 (10.8)	58.9 (10.2)	58.5 (11.5)	63.0 (10.5)	0.07
Male (%)	94.7	95.9	98.0	90.2	0.19
Race/ethnicity (%)					
Non-Hispanic white	74.2	69.4	74.5	78.4	0.93
Non-Hispanic black	12.6	12.2	11.8	13.7	
Hispanic	9.3	12.2	9.8	5.9	
Other	2.7	4.1	2.0	2.0	
No response	1.3	2.0	2.0	0.0	
Employment status (%)					
Employed	23.8	20.4	17.7	33.3	0.26
Retired	57.0	57.1	58.8	54.9	
Other	19.1	22.5	23.5	11.8	
Marital status (%)					
Married/partnered	49.0	40.8	52.9	52.9	0.50
Separated/divorced or widowed	32.5	30.6	33.3	33.3	
Single	14.6	22.5	11.8	9.8	
No response	4.0	6.1	2.0	3.9	
Highest grade completed (%)					
Less than high school graduate	9.5	14.9	6.1	7.8	0.52
Completed high school	28.6	31.9	28.6	25.5	
Some college	36.1	31.9	42.9	33.3	
College graduate or higher	25.9	21.3	22.5	33.3	
Years since diabetes diagnosis (%)					
Less than 1 year	2.1	2.3	2.1	2.0	0.91
1–5 years	19.0	25.0	16.7	16.0	
6–10 years	29.6	27.3	27.1	34.0	
More than 10 years	49.3	45.5	54.2	48.0	

[a]P values are from one-way analysis of variance (continuous variables) and χ^2 tests (categorical variables).

TABLE 2. CHANGES IN OUTCOME VARIABLES OVER A 12-MONTH PERIOD

Parameter	Baseline	12 months	Difference[a]	P[b]
A1c (%)				
Online care	9.6±1.0	8.3±1.1	−1.3±1.4	<0.0001
Telephone care	9.9±1.2	8.5±1.6	−1.5±1.6	<0.0001
Web training	10.1±1.4	8.4±1.7	−1.7±1.8	<0.0001
Systolic BP (mm Hg)				
Online care	135.6±17.4	135.2±19.2	−0.3±16.9	0.891
Telephone care	139.9±17.4	133.2±17.1	−6.7±16.7	0.006
Web training	139.8±19.1	136.7±19.3	−3.1±20.4	0.297
Diastolic BP (mm Hg)				
Online care	75.7±11.8	73.2±10.7	−2.5±12.9	0.178
Telephone care	80.8±13.1	74.6±10.7	−6.3±11.5	0.001
Web training	83.1±15.8	77.3±11.5	−5.8±15.5	0.012
Total cholesterol (mg/dL)				
Online care	172.3±35.9	164.6±32.7	−7.8±29.3	0.071
Telephone care	167.6±42.7	158.3±35.1	−8.5±29.3	0.048
Web training	174.0±38.2	163.1±38.0	−10.7±29.8	0.019
LDL (mg/dL)				
Online care	95.1±29.4	92.4±27.4	−4.0±25.8	0.290
Telephone care	91.7±37.8	85.9±27.1	−5.5±24.1	0.122
Web training	92.5±32.3	86.3±29.4	5.8±24.6	0.118
HDL (mg/dL)				
Online care	39.1±10.6	39.7±11.6	0.8±6.8	0.413
Telephone care	39.0±12.0	37.2±11.2	−2.1±4.1	0.001
Web training	38.1±10.0	38.0±10.2	−0.2±5.7	0.848
Triglycerides (mg/dL)				
Online care	190.5±85.8	163.6±75.1	−25.5±66.3	0.010
Telephone care	186.4±127.6	176.3±133.4	−6.5±108.7	0.676
Web training	225.5±139.6	197.2±117.7	−26.4±98.5	0.076
Weight (pounds)				
Online care	232.9±46.2	234.3±48.0	1.4±13.5	0.458
Telephone care	235.2±55.3	239.1±55.7	4.0±14.8	0.062
Web training	235.6±52.2	237.5±48.8	0.7±15.1	0.747
BMI (kg/m^2)				
Online care	34.4±6.1	34.5±6.2	0.2±2.1	0.551
Telephone care	33.7±7.3	34.3±7.4	0.6±2.2	0.066
Web training	34.2±7.0	34.3±6.4	0.1±2.2	0.725
Diabetes distress				
Online care	21.8±21.0	19.2±18.5	1.8±10.7	0.271
Telephone care	24.5±20.0	18.3±15.7	6.2±15.0	0.008
Web training	29.0±19.6	19.5±14.8	8.0±15.6	0.003

[a]Difference scores were computed for subjects with complete data at baseline. This limitation applied to the lipid values and distress scores only. Rounding affected the difference scores slightly for some parameters.
[b]P values are from paired t tests comparing baseline means with 12-month means within each study group.
A1c, hemoglobin A1c; BMI, body mass index; BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

The engagement of patients with care managers in the intervention groups was not clearly associated with the reduction in A1c or any other health outcome assessed. We separated participants into groups with varying amounts of contact with care managers over the course of the study. Participants in the telephone care group with ≤3 (23%), 4–6 (29%), 7–9 (37%), and >9 (10%) months of successful care manager contact had, respectively, quarterly A1c differences over 12 months of −1.3%, −1.7%, −1.5%, and −1.1%. Participants in the online care group with ≤3 (18%), 4–6 (24%), 7–9 (47%), and >9 (12%) months of successful care manager contact had A1c differences over 12 months of −0.2%, −1.4%, −1.8%, and −0.8%, respectively.

With regard to engagement with the care management Web site, participants in the online care group with ≤3 (18%), 4–6 (14%), 7–9 (25%), and >9 (43%) months of logins to the care management site had, respectively, quarterly A1c differences over 12 months of −0.6%, −1.3%, −1.7%, and −1.5%. Participants with the highest and the lowest frequency of logins had similar changes in A1c.

Changes in parameters were assessed within study groups. Systolic and diastolic blood pressures significantly decreased within the telephone care group, diastolic blood pressure, total cholesterol, and diabetes distress significantly decreased within the telephone care and Web training groups, high-density lipoprotein cholesterol significantly decreased within

FIG. 2. Change in hemoglobin A1c (HbA1c) in each of the three study groups over time.
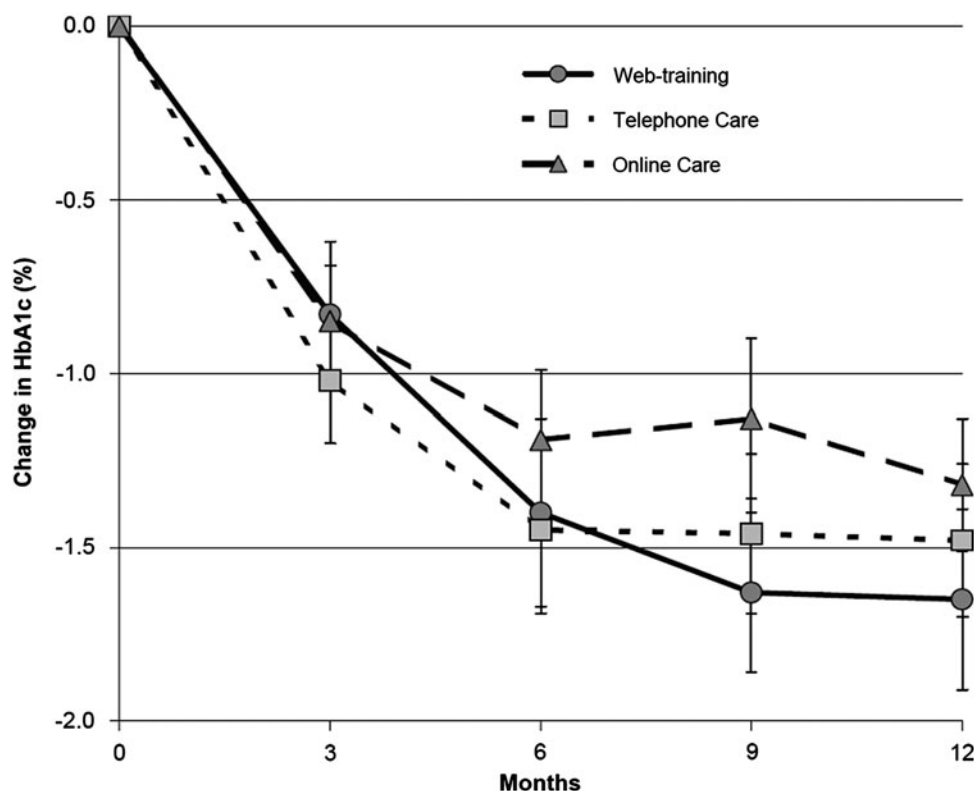
the telephone care group, and triglycerides significantly decreased within the online care group (Table 2). Weight increased similarly in all groups, ranging from 0.7 to 4.0 pounds. According to the multilevel model results, none of these parameters was significantly different among groups over time. The frequency of provider contacts and usage of the care management portal were not associated with changes in these variables.

Discussion

In this study we evaluated the effectiveness of two care management strategies in patients with elevated A1c in comparison with a Web training group that was provided with a computer and Internet access. Over a 12-month period, A1c improved by 1.2% or greater among all study groups whether or not active care management was offered. The results of this study show that telephone or online care management offered no additional benefits for a variety of diabetes outcomes compared with training in the use of online self-management resources.

Our study suggests that providing access to online resources for patients with poorly controlled diabetes improves outcomes to the same degree as active care management. This builds on prior studies that demonstrated the efficacy of engaging patients in their self-care.[7–9] We and others have previously shown that self-management education alone can result in significant improvement in A1c and that online care management is associated with significantly reduced A1c compared with usual care in patients with poorly controlled diabetes.[4,10,23–25] A meta-regression analysis of quality improvement strategies in patients with diabetes suggested that case management by individuals with expanded roles (e.g., advanced practice nurses or clinical pharmacists) resulted in

significant declines in A1c.[26] It has not been previously possible to determine which component of the provided care leads to the improvement in diabetes measures.

With the growing ubiquity of online resources to help keep patients engaged in self-care for chronic diseases, this study builds on prior research that suggests that directing patients to these online resources and providing training in its use may have an important role in chronic disease management.[18,27] The robust A1c responses in each group, with an average 1.5% A1c decrement, support the efficacy of improving self-efficacy using online technology.

Web-based learning can benefit both patients and their care providers because time between visits can be used effectively and efficiently to learn self-supporting behaviors that reinforce clinician recommendations. The patient can use these resources and engage in peer-sharing to learn to overcome barriers and to self-document activities. An emerging array of studies has demonstrated that the most effective online self-management education and support programs are rich in content, provide engaging interactive elements, and can tailor the learning to a patient's individual needs.[3,10] Encouraging patients to access a series of informational Web sites is substantially less resource intensive than care management. The results of this study suggest that facilitating access to online information is likely to be much more cost-effective than active care management.

Several factors should be considered in interpreting the results of this study. Although we used broad eligibility criteria to produce potentially generalizable findings, the education level of study participants was fairly high, with only 9.5% of participants having less than high school education and 25.6% having completed college. Thus, the enrolled participants may have self-selected into the study because of its

focus on online interventions, and this may have affected their use of online resources. Small sample sizes limit the ability to perform more detailed subgroup analyses. The study hypothesis required an open-label design, and participating in a study may itself have prompted behavioral changes that affected outcomes similarly in all groups. In addition, diabetes care in the VA system has improved substantially over time, attributed to increased use and dissemination of performance measures, clinical reminders, and data tracking.[28–30] The study was conducted during a period of system-wide declines in A1c. These possibilities would bias the study in favor of similar improvement across groups and in favor of the null hypothesis of no differences between groups.

Our results do raise questions whether care management, regardless of its delivery method, contributes substantively to the care of patients with poorly controlled diabetes above and beyond the gains attained by connecting patients with supporting resources. These results reinforce the imperative to perform appropriately controlled, randomized studies before assuming that care management technologies are cost-effective regardless of how novel the technology may appear. Clinical programs seeking to augment and improve diabetes care may be more effective when efforts are channeled to increasing information exchange and engagement of patients with their own disease management. These results support our prior findings that patient engagement is a key factor driving improved glucose control, and our results indicate that improvement in diabetes care measures may be naive to the mode of engagement.

In summary, the results from this study show that in patients with elevated A1c, active care management whether delivered via telephone or online methods has no significant additional benefit compared with access and training in the use of online diabetes self-management resources. An important implication of these results is that simple measures to improve self-efficacy by engaging patients in the use of self-management resources may be just as effective as active care management.

Acknowledgments

Author Disclosure Statement

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