Web-Based Care Management in Patients With Poorly Controlled Diabetes

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OBJECTIVE — To assess the effects of web-based care management on glucose and blood pressure control over 12 months in patients with poorly controlled diabetes.

RESEARCH DESIGN AND METHODS — For this study, 104 patients with diabetes and HbA_{1c} (A1C) ≥9.0% who received their care at a Department of Veterans Affairs medical center were recruited. All participants completed a diabetes education class and were randomized to continue with their usual care ($n = 52$) or receive web-based care management ($n = 52$). The web-based group received a notebook computer, glucose and blood pressure monitoring devices, and access to a care management website. The website provided educational modules, accepted uploads from monitoring devices, and had an internal messaging system for patients to communicate with the care manager.

RESULTS — Participants receiving web-based care management had lower A1C over 12 months ($P < 0.05$) when compared with education and usual care. Persistent website users had greater improvement in A1C when compared with intermittent users (−1.9 vs. −1.2%; $P = 0.051$) or education and usual care (−1.4%; $P < 0.05$). A larger number of website data uploads was associated with a larger decline in A1C (highest tertile −2.1%, lowest tertile −1.0%; $P < 0.02$). Hypertensive participants in the web-based group had a greater reduction in systolic blood pressure ($P < 0.01$). HDL cholesterol rose and triglycerides fell in the web-based group ($P < 0.05$).

CONCLUSIONS — Web-based care management may be a useful adjunct in the care of patients with poorly controlled diabetes.

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Diabetes care is facilitated by a patient's being engaged in a self-management program with the advice and counsel of physicians and allied health professionals (1). Care management has been advocated in diabetic patients as a means of facilitating easier, time-efficient communication between clinicians and patients, with the goal of improving care and reducing healthcare expenditures.

Healthcare systems have adopted care management for individuals with high-risk diseases, particularly patients with diabetes (2–5). Scheduling and/or travel may be barriers to a patient's engaging with a care provider, thereby limiting uptake and resulting in a failure to maximize potential health gains (6). Care management has been studied in diabetic patients, but the results have been mixed; some have noted significant improvement in HbA_{1c} (A1C) (7–9), but a recent study found no effect (10).

Patients are accessing medical content on the Internet with increasing frequency (11–14). In a survey of patients in a primary care practice, 54% reported using the Internet for medical information and 60% felt that the information was the same or better than what they received from their doctor (11). Few studies have examined the effects of web-based interventions that provide an interactive component; that is, websites that deliver content as well as feedback to participants (15–17). Our goal was to test the hypothesis that diabetes care management using a web-based system in individuals with poorly controlled diabetes would result in significant and sustained improvement in A1C and blood pressure.

RESEARCH DESIGN AND METHODS

— 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 ≥9.0%, age >18 years, an ability to understand written and spoken English, and a 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 and access to a telephone.

Hospital laboratory data were screened monthly for individuals with an A1C ≥8.8%. Potential participants were sent a letter and/or brochure describing the study, and a follow-up telephone call was attempted at least 2 weeks later to solicit participation. In-person screening was provided to interested and potentially eligible subjects between October 2001 and April 2003 (Fig. 1). Reasons for nonparticipation, as provided by 353 of the

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Abbreviations: VA, Department of Veterans Affairs.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

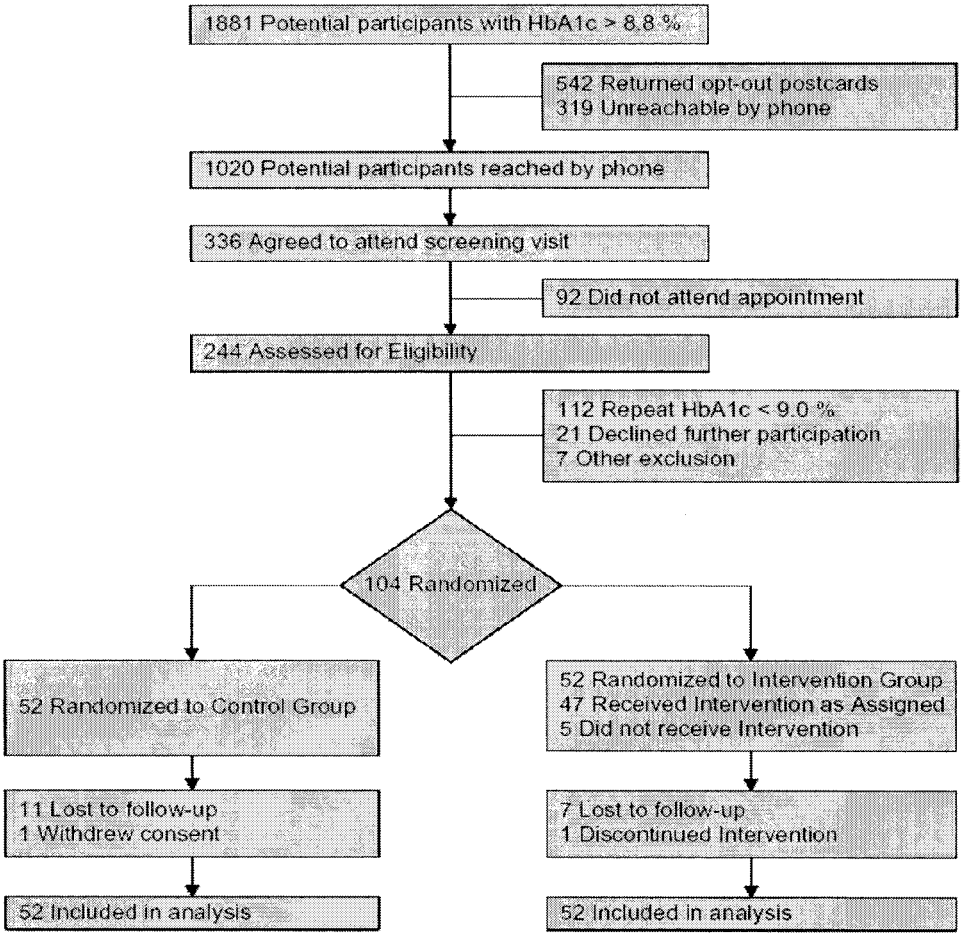

Figure 1—*CONSORT diagram of participant flow through the study.*

684 individuals who declined to participate after being reached by phone, included a lack of interest (30%), transportation challenges (25%), poor health (20%), scheduling difficulties (9%), and other (16%).

Eligible participants attended a half-day self-management education session for instruction in diabetes core-content areas as recommended by the American Diabetes Association (18). They met with a nurse, nutritionist, and pharmacist, all of whom were certified diabetes educators. Participants were then randomized to one of two study groups through the use of a random variables generator and a series of sealed envelopes.

Participants randomized to usual care continued with ongoing care by their primary care provider as needed. Study staff had contact with these participants only to arrange follow-up visits for outcome measures.

Participants randomized to web-based care management also continued with their usual care but in addition received a notebook computer (HP Omnibook, 700 mHz, 128 RAM, running Internet Explorer 5.50), a glucose meter (Accucheck Advantage, Roche Diagnostics), and a blood pressure monitor (HEM-747-IC IntelliSense Automatic BPM; Omron Medical, North Bend, WA). The notebook computer was programmed to connect to a diabetes education and management website (see below) using complimentary toll-free dial-up Internet access. Computer training and support was provided by one of the study staff (S.H.H.) for a mean total of 2.3 h (range 1.0–6.6 h) per subject. Subjects were encouraged to perform home blood pressure monitoring at least three times weekly; recommendations for home glucose testing were individualized for each patient.

The MyCareTeam website (https://mycareteam.georgetown.edu/vaboston) was designed and hosted at the Imaging Science and Information Systems Center at Georgetown University Medical Center (Washington, D.C.). Participants used coded identifiers when interacting with the website, which was accessed using secure socket layer encryption via a secure protocol to ensure the confidentiality of data transfer. The website accepted uploads from blood pressure and glucose monitoring devices and displayed these data in graphic and tabular form for the participant and care manager to review. An internal messaging system allowed participants to send and receive secure messages to and from the care manager via the website. The care manager responded to queries within 1 working day during office hours. The website contained web-enabled diabetes educational modules and had links to other web-based diabetes resources. Participants who did not log into the website during any 2-week period were contacted by a study coordinator by telephone to encourage website usage.

An advanced practice nurse and certified diabetes educator (H.E.G.) reviewed participant data from the website and, using treatment algorithms for glucose and hypertension management, pro-

Table 1—*Baseline characteristics of study subjects*

	Web-based care management	Education and usual care
n	52	52
Age (years)	64 ± 7	63 ± 7
Sex (% male)	99	100
BMI (kg/m^2)	32.3 ± 5.6	34.1 ± 7.0
Education (%)		
College or above	59	67
High school graduate	22	19
Some high school	12	6
Below high school	6	2
Prior Internet access (%)	31	27
Duration of diabetes (years)	12.4	12.2
Diabetes medication		
Oral medication only	27 (52)	26 (50)
Insulin	25 (48)	26 (50)
Mean A1C (%)	10.0 ± 0.8	9.9 ± 0.8
Blood pressure (mmHg)		
Systolic	141 ± 21	139 ± 20
Diastolic	81 ± 7	80 ± 7
Lipids (mg/dl)		
LDL cholesterol	100 ± 35	97 ± 21
HDL cholesterol	43 ± 14	40 ± 8
Triglycerides	178 ± 112	204 ± 140

Data are means ± SD or *n* (%), unless otherwise noted.

vided recommendations to the primary care provider and participants. The care manager and primary care providers communicated predominantly via the hospital e-mail system; the physician entered medication changes suggested by the care manager directly into the pharmacy's electronic ordering system. The care manager and participants maintained contact through the website's internal messaging system and occasionally through telephone contact.

Outcome measures

The primary outcome measures were A1C and systolic and diastolic blood pressure. Measurements were collected at baseline and 3, 6, 9, and 12 months after randomization. For measurement of A1C, the hemoglobin components were separated using high-performance liquid chromatography, and the six fractions of hemoglobin, including the A1C component, were measured (Tosoh Bioscience, South San Francisco, CA). Blood pressure was measured in the seated position after a 5-min rest with the same automatic blood pressure device used by study participants at home. Two readings were taken 1 min apart and the average of the readings was recorded. Hypertension was defined as systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg, measured at baseline. Secondary outcome measures (fasting triglycerides and LDL and HDL cholesterol) were obtained at baseline and 12 months and were measured with standard laboratory techniques. Research staff recording outcome measures were not masked to study group assignment.

The protocol prespecified an evaluation of outcomes in the web-based group based on the frequency and persistence of website interactions. During the study, website log-ins and data uploads were counted and time stamped. The number of data uploads over the 12 months of follow-up was separated into tertiles representing medians of 1, 18, and 31 uploads. Persistence with the web-based care management over time was assessed by defining individuals as a "persistent user" (i.e., those who had at least one website log-in every 3 months; $n = 30$) or an "intermittent user" (i.e., those who had intervals >3 months during the study when no website log-ins were recorded; $n = 22$).

Statistical analyses

A sample size of 50 participants in each group was determined to have 80% power ($\alpha = 0.05$) to detect a between-group difference of 0.8% for A1C, 6 mmHg for systolic blood pressure, and 5 mmHg for diastolic blood pressure. Categorical data are presented as percent and continuous data are presented as means ± SD, unless otherwise noted. All analyses compared subjects according to their status at randomization and were conducted in an intention-to-treat manner, with the last value carried forward for missing data. Baseline characteristics were compared using the χ^2 analysis for categorical variables and the independent groups' *t* test for continuous variables.

Differences between baseline and follow-up for continuous variables were assessed using a mixed linear model incorporating the grouping variable (i.e., randomization or persistence group) as a fixed effect and repeated measures analysis to specify covariance structures for repeated measurements on subjects over time. All tests were two-tailed. For all analyses, $\alpha = 0.05$ was used to define statistical significance. Statistical analysis was performed using SAS 8.02 (SAS Institute, Cary, NC).

RESULTS

Baseline characteristics of the 104 randomized participants, divided by study group, are presented in Table 1. The mean age was 63 years; nearly all were men. The data showed that >50% of the study participants had attended college and ~29% had Internet access before the study.

Changes in A1C

There was a significant decrease in A1C compared with baseline in both groups ($P < 0.001$) at all serial points of measurement (Fig. 2). There was a greater decline in A1C over time in the web-based group when compared with the usual care group ($P < 0.05$). At 12 months, the reduction from baseline in A1C was −1.2 ± 1.4% in the usual care group versus −1.6 ± 1.4% in the web-based group.

Individuals who had greater adherence with the intervention had more improvement in A1C. Participants in the web-based group who had more data uploads or regular website interactions had greater improvements in A1C. Persistent users tended to have a greater change in A1C when compared with intermittent users (−1.9 ± 1.2 vs. −1.2 ± 1.4%; $P = 0.051$) or the usual care group ($P < 0.05$) that persisted over time (Fig. 3*A*). Simi-

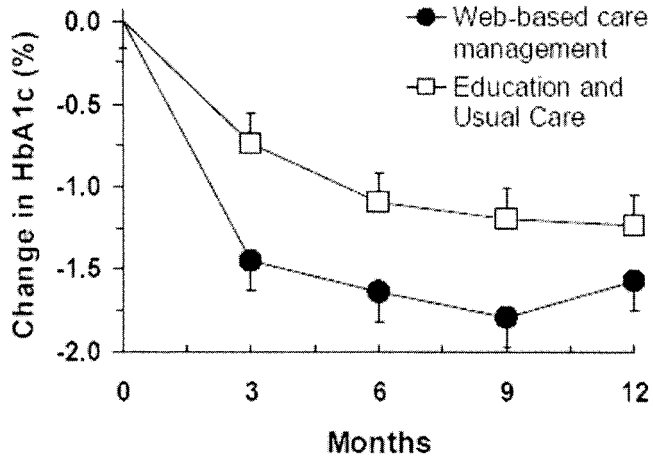

Figure 2—*Changes in A1C over 12 months in the usual care and web-based groups. Participants in the web-based group had a significantly greater change in A1C over time* ($P < 0.05$) *when compared with the usual care group. Data are means ± SE.*

larly, there was a progressive decline in A1C with an increasing number of website data uploads (Fig. 3*B*). Those in the highest tertile for data uploads had a significantly greater decline in A1C than those in the lowest tertile (-2.1 ± 1.1 vs. $-1.1 \pm 1.7\%$; $P < 0.05$). Persistent and intermittent users and those who had greater or fewer data uploads did not differ with regard to baseline demographic or biochemical parameters.

A similar numbers of participants in each group experienced severe hypoglycemia during the study, defined as an episode of hypoglycemia that required assistance from another person (web-based: 46 events in 13 participants [median: 3 per participant]; usual care: 33 events in 11 participants [median: 2 per participant]).

Changes in blood pressure

Treatment for hypertension was targeted by the web-based care management intervention. Hypertensive participants in the web-based group ($n = 37$) had a significantly greater decline in systolic blood pressure after 12 months when compared with the usual care group ($n = 35$) (-10 ± 17 vs. -7 ± 21 mmHg; $P < 0.01$). Diastolic blood pressure declined similarly in both groups (web-based group: -5 ± 13 mmHg [$P = 0.053$ vs. baseline]; usual care group: -6 ± 11 mmHg [$P = 0.058$ vs. baseline]). The frequency of website log-ins or data uploads was not a predictor for change in blood pressure over time. At the end of the trial, there were fewer hypertensive participants in the web-based group ($n = 28$) than in the usual care group ($n = 37$).

Changes in lipid profiles

LDL cholesterol was analyzed as a secondary end point and did not change in either group (web-based group: -6 ± 12 mg/dl; usual care group: -5 ± 11 mg/dl). However, web-based care management was associated with a significant increase in HDL cholesterol (3 ± 6 mg/dl; $P < 0.05$ vs. baseline) and a significant decrease in triglyceride levels (-38 ± 99 mg/dl; $P < 0.01$ vs. baseline); these values did not change in the usual care group (1 ± 6 mg/dl and -2 ± 60 mg/dl, respectively).

CONCLUSIONS

— More than most chronic diseases, diabetes often requires behavioral and medication changes supported by frequent feedback and support from care providers. We and others have previously shown that self-management education alone can result in significant improvement in A1C in patients with poorly controlled diabetes (19–21). In this study, we used broad eligibility criteria to produce potentially generalizable findings. Most of our study participants had no prior computer experience and/or Internet access. For the subjects who had elevated A1C, self-management education coupled with Internet access, technology training, and web-based care management resulted in significant improvements in A1C over 12 months when compared with education and usual care. Individuals who persisted with website usage and regular data uploads were more likely to achieve and maintain reductions in A1C. Additional improvements were seen in lipid profiles and systolic blood pressure in hypertensive participants. These findings support a role for web-based care management in patients with elevated A1C as a tool for improving diabetes care.

Several factors should be considered in interpreting the results of this feasibility study. Not every clinical practice setting has access to a care manager with similar training and experience as was available in this study, although such allied health professionals are likely to be-

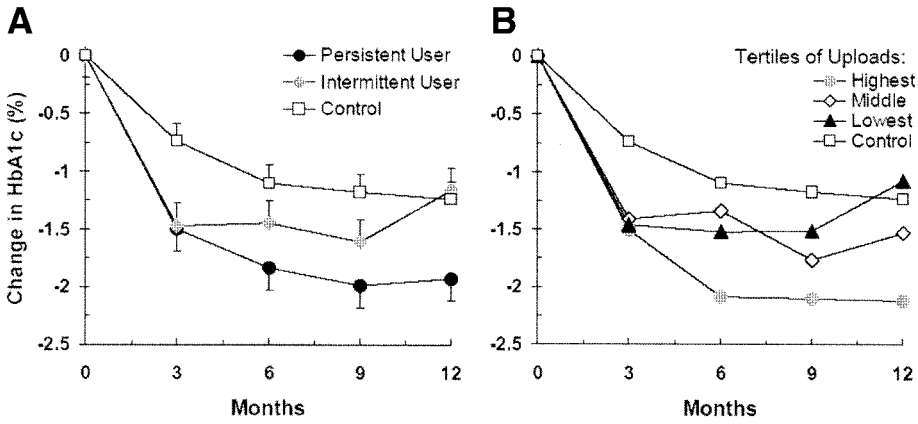

Figure 3—*Effects of engagement with web-based care management and outcome.* A*: Changes in A1C in the web-based group who were persistent and intermittent users in comparison with the usual care group. Persistent users had a substantially greater fall in A1C compared with intermittent users and a significantly greater effect versus those receiving education and usual care. Data are means ± SE.* B*: Changes in A1C in the web-based group by tertiles of website data uploads during the study. (Median number of uploads for each tertile: lowest = 1 upload; middle = 18 uploads; highest = 31 uploads.) A larger number of data uploads was associated with a larger decline in A1C.*

come increasingly prevalent. We were able to provide Internet access and computer training to study participants, which may not be available to some patients. There was a low prevalence of women recruited into this study, reflecting the relatively smaller number of women cared for in the VA healthcare system. Previous studies (7,8) with a more balanced enrollment of men and women receiving care management have shown similar outcomes between men and women. The study question necessitated an open-label design that may have been subject to the Hawthorne effect and confounding factors. The observation that the degree of improvement in A1C correlated with level of interactivity with the website could reflect an underlying change in motivation of the participants rather than use of the care program per se. Consequently, although the evidence linking website use and outcome is noteworthy, the mechanism through which the care management program achieved its success remains speculative.

There was significant improvement in A1C among those randomized to education and usual care. The VA healthcare system has progressively improved its diabetes care program through a series of successful initiatives (22,23). In addition, the laboratory results obtained for this study were available on the VA electronic medical record database and could have resulted in targeted care that might not have been offered in its absence.

Care management has been embraced for patients with high-risk and/or high-cost medical conditions such as diabetes, with claims of significant cost savings (2,3). However, the cost-effectiveness of care management in diabetes is still a matter of debate. Indeed, a recent analysis of potential interventions in diabetic patients concluded that care management has an unclear economic impact (24). Nevertheless, care management has been recommended by the Task Force on Community Preventive Services of the Centers for Disease Control and Prevention (25). Although a detailed economic analysis is clearly warranted, our study results show the effectiveness of such an approach, particularly among individuals interested in engaging with the technology.

The Internet has clearly become the gateway to limitless health information (11–14). However, few studies have evaluated the clinical benefit of using web-based education and/or healthcare provider feedback. Access to an interactive asthma education website resulted in a significant increase in asthma knowledge and reduced numbers of symptom-days, emergency room visits, and inhaled corticosteroid doses (26). In a trial linking web-based education with health care provider feedback, overweight and obese adults randomized to web-based behavioral counseling or basic Internet access achieved significantly greater weight loss when receiving web-based provider feedback intervention (15).

The major advantages of a web-based care management program are the ability to post professionally vetted material on secure websites, 24 h accessibility, and availability to individuals in their home without regard to the distance from their site of healthcare. Our results support the development and greater study of this increasingly ubiquitous portal in the management of patients. Patients with poorly controlled diabetes who adopt such a system and regularly exchange information with their healthcare providers are likely to derive important clinical benefits.

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