DIABETES TECHNOLOGY & THERAPEUTICS
Volume 6, Number 6, 2004

Impact of MyCareTeam™ for Poorly Controlled Diabetes Mellitus

KAREN E. SMITH, M.D.,[1] BETTY A. LEVINE, M.S.,[2] STEPHEN C. CLEMENT, M.D.,[3] MING-JYE HU, M.S.,[2] ADIL ALAOUI, M.S.,[2] and SEONG K. MUN, Ph.D.[2]

ABSTRACT

Objective: Web-based diabetes management can be used to provide frequent interactions between patients and providers and thus result in improved glycemic control.

Methods: In a single-center, prospective feasibility study, 16 poorly controlled patients with either type 1 or 2 diabetes mellitus were enrolled to assess the impact of using MyCareTeam™, a web-based diabetes management application, for diabetes management. Patients were asked to transfer their blood glucose data electronically, maintain exercise logs, and communicate with their provider via MyCareTeam. The provider gave clinical interventions to optimize blood glucose control and provided feedback via MyCareTeam. Diabetes, nutrition, and exercise information was also available via MyCareTeam.

Results: A significant reduction of over 2.22% points in hemoglobin A1C was seen for the total patient population. Differences between moderate/heavy users ($n = 8$) versus light/never users ($n = 8$) of MyCareTeam were evaluated for intergroup differences based upon utilization. Moderate/heavy users had a significant 6-month A1C reduction of 3.15 percentage points compared with a reduction of 1.28 percentage points in light/never users. Other secondary end points were improved as well, including systolic blood pressure, diastolic blood pressure, total cholesterol, high-density lipoprotein, low-density lipoprotein, and triglycerides. However, as expected, body mass index levels increased because of aggressive diabetes management with insulin therapy.

Conclusions: These results demonstrate a significant treatment effect from the MyCareTeam application. A larger randomized control trial is under way at the Boston Veterans Administration Healthcare System. If these results are confirmed as expected, then web-based diabetes management may prove to be the link to achieving target American Diabetes Association glycemic goals in patients with poorly controlled diabetes.

INTRODUCTION

RESULTS FROM the Diabetes Control and Complications Trial[1] and the United Kingdom Prospective Diabetes Study[2] show the importance of maintaining near-normal blood glucose levels to prevent complications of diabetes. Despite newer therapeutic agents and regular interventions from primary care physicians and subspecialists, obtaining optimum glycemic control remains a challenge.[3] In previous studies better glycemic control is associated

[1]Medical Associates, Canton, Georgia.
[2]ISIS Center and [3]Department of Endocrinology and Metabolism, Georgetown University Medical Center, Washington, D.C.

with reduced rate of admissions for selected short-term complications with subsequent reduced medical charges for these complications over a 3-year period. The potential short-term economic benefits are important to consider when making decisions regarding the adoption and use of new interventions for the management of diabetes.[4] In addition to better health outcomes, strategies that improve control may have substantial economic benefits in reducing healthcare costs.

Telemedicine has various applications in diabetes care, including as a method of increasing efficacy of patients' self-management that may lead to improved glycemic control.[5,6] Telemedicine systems improve communication of the patient with the hospital-based diabetologist, allowing doctors to assess the patient's data frequently with needed interventions. It provides patients with provider-based support as they learn their disease and make appropriate changes in their care under the provider's guidance. This fosters the needed independence that will aid in obtaining glycemic control targets.[7]

Diabetes management using computer technology has the potential to improve clinical outcomes as compared with conventional therapy. A study using a computer voice-activated system available for physician-directed management 24 h daily showed that with its use hemoglobin A1C levels were reduced by 1.0–3.0% in patients actively using the system compared with controls. In addition, diabetes-related crises (hyperglycemia or hypoglycemia) were reduced.[8] In another study looking at time and cost savings using telemanagement for patients on intensified insulin therapy investigators found an increase in time spent by physician for telemanagement compared with conventional management moderately higher. However, a cost savings of approximately 650 Euro per patient was seen as well as a significant decrease in A1C from 8.2% to 7.0% after 8 months of observation.[9] Their study used glucose meters and telephone modems to transfer blood glucose readings to a physician for review. The physicians displayed and reviewed the readings using special software and then contacted the patients via telephone every 2–4 weeks for consultation. Chase et al.[10] showed that electronic transmission of blood glucose values and other clinical data every 2 weeks reduced costs associated with clinic visits and showed no significant differences in A1C or mild to moderate hypoglycemic events.

In the past decade, computer-assisted interventions, using Web-based telemedicine technology, have been developed for a variety of behavior changes, including dietary change,[11–13] smoking cessation,[13,14] and exercise.[13,15] Several studies have shown that telemedicine has proven beneficial for the population with diabetes in A1C reduction with dietary changes[16] and changes in intensive insulin therapy in pregnant women with diabetes.[17]

The target population we chose to study was patients with type 1 and type 2 diabetes having chronic poor control. Our hypothesis is that the standard model of follow-up visits every 2–3 months may not be sufficient to achieve American Diabetes Association (ADA) glycemic target goals for patients with poor control. This subset of patients with diabetes may need a shorter "intervention interval" ($INTV_I$) (weekly vs. monthly interval changes) in order to achieve and maintain ADA target goals. To achieve this, we designed an interactive web-based program called MyCareTeam™. Web-based systems allow the patient to become an integral part of the healthcare team. Their diabetes control improves with more frequent interventions and by providing more opportunities for education in their disease process so they can make appropriate behavioral changes needed for better glycemic control.

RESEARCH DESIGN AND METHODS

A nonrandomized prospective feasibility study of 16 patients with poorly controlled type 1 or type 2 diabetes mellitus was undertaken. The Institutional Review Board at Georgetown University Medical Center (Washington, DC) approved this study, and written informed consent was obtained from all participants. The study consisted of 16 type 1 and type 2 patients with diabetes ranging in age from 19 to 65 years who had failed to obtain glycemic control with conventional follow-up at the Georgetown University Endocrine Clinic. The study dura-

tion was from December 2000 to August 2001. Patients were eligible for the study if: (1) they were 18 years or older; (2) they had been diagnosed with type 1 or type 2 diabetes for at least 1 year; (3) they did not have unstable cardiac disease or history of organ transplantation; (4) they were capable of reading a computer monitor; and (5) they had A1C values greater than 8.5% for the preceding 6 months.

Study design and data collection

After informed consent was obtained, patients who met the entry criteria had an initial comprehensive evaluation by a physician or nurse educator. Specific metabolic and behavioral goals that enhance the patient's health were discussed. Patients were scheduled for baseline, 3-month, and 6-month clinic visits as routine care. Baseline labs and 6-month complete metabolic panel, including fasting lipid profile and urine microalbuminuria:creatinine ratio, and patient surveys were obtained at these clinic visits. Blood pressure (BP), body mass index (BMI), and A1C were also obtained at baseline, 3 months, and 6 months. During these visits the patients met with the physician to discuss current health status and any needed treatment adjustments. Between clinic visits the patient could use the MyCareTeam program to interact with their provider via the Internet. The patients uploaded their blood glucose and exercise data, and communicated via the web site weekly. The provider gave subsequent clinical interventions to optimize blood glucose control, and provided feedback via MyCareTeam, including suggestions regarding diet, exercise, or medication changes. MyCareTeam also provided general diabetes, nutrition, and exercise information.

Patients and their care providers used the messaging components of MyCareTeam to communicate clinical concerns in between scheduled office visits. Patients could type in comments about their blood sugar readings when they uploaded them to the MyCareTeam database. The provider responded directly to those comments within the summary page of MyCareTeam (Fig. 1), and the comments were available to the patients when they next entered the site. There is also a more standard e-mail type of messaging built into MyCareTeam that was used by patients and providers. This permits a secure exchange of messages between the patients and providers that is consistent with the Health Insurance Portability and Accountability Act (HIPAA) regulations.

MyCareTeam follows the HIPAA rules and regulations, which require clinical data integrity, security, and confidentiality. MyCareTeam follows the HIPAA requirements for: (1) data access; (2) data loss; (3) authentication/authorization; (4) audit; and (5) confidentiality. The database is located inside a locked room accessible only through keypad or smartcard entry. A firewall protects the computers housing the database and MyCareTeam applications from unauthorized electronic access. To protect against data loss, daily incremental backups of the database and MyCareTeam applications are performed along with weekly full backups. All data stored in the database are protected by login/password authentication and access controls. User's access to the data is controlled by their login code. This ensures that patients and their providers see only their data. Login information and access to data within the database are tracked. Login and logout times and when and who uploaded data were tracked as well as access to data so that it is always known who did what to the data and when.

Patients and their providers access MyCareTeam via the World Wide Web using a secure socket layer connection, 128-bit encryption, and secure HTTP for all transactions that include protected health information including demographics, clinical information, or messaging. Data uploaded from the participant's glucose meter do not contain identifying information and are uploaded only after a participant has been authenticated into MyCareTeam. This transfer to the database is through the encrypted link, and the data are associated with the correct patient in the database through their login identifier.

Measures

The primary outcome variable measured was A1C. Secondary outcome variables included BP, BMI, total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein

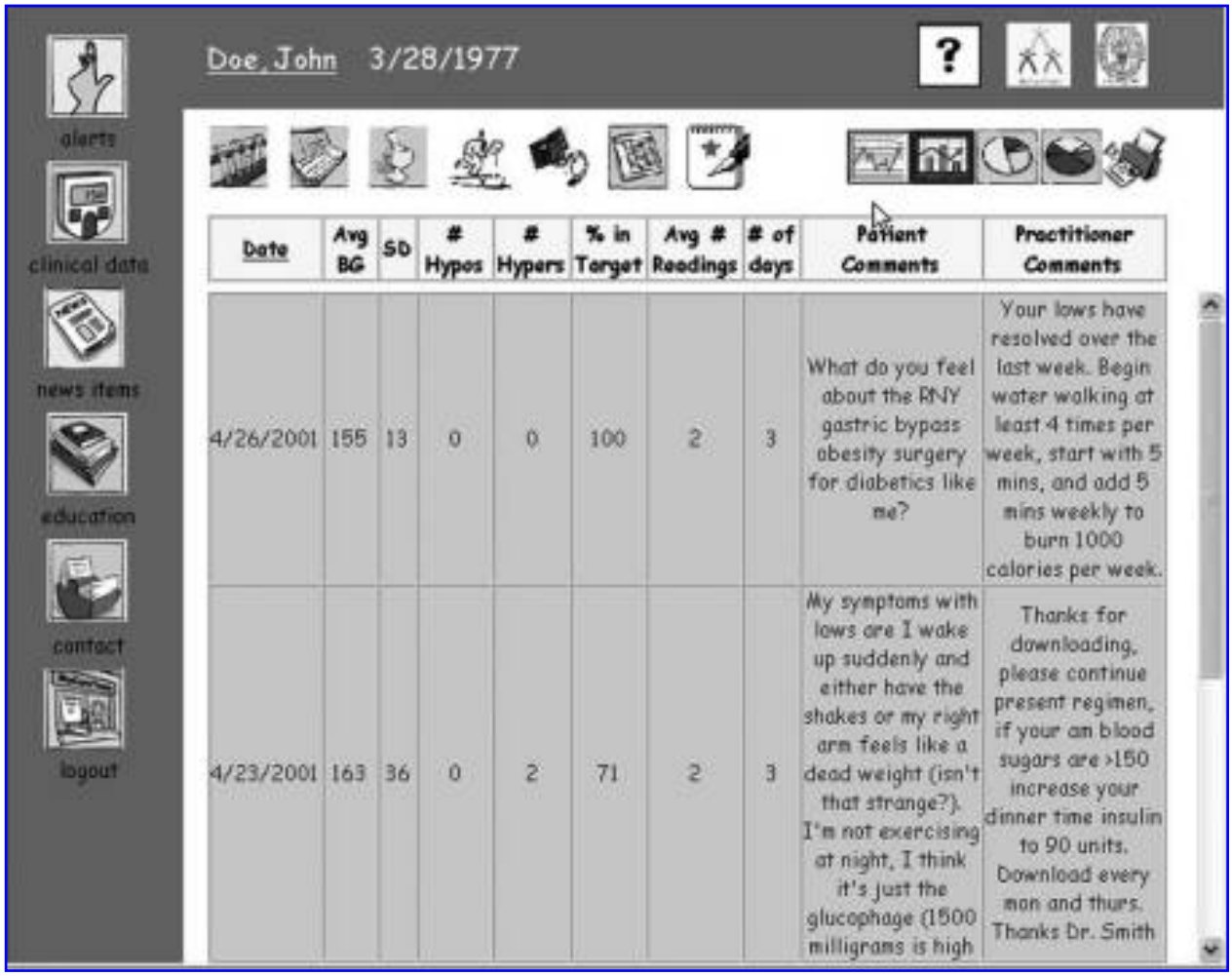

FIG. 1. One-messaging component within MyCare Team.

(LDL), and triglycerides (TG). The Summary of Diabetes Self-Care Activities, Diabetes Treatment Satisfaction Questionnaire: DTSQ and Diabetes Quality of Life Measure Surveys were also obtained.[18,19] Results of the surveys are not presented here. Comparisons of the various end points were observed between those who used the site regularly and those who did not.

Statistical analysis

In this analysis we attempted to establish a relationship between a dichotomous exogenous variable (use of MyCareTeam) and a series of endogenous measures that includes BP, BMI, and A1C. Because of the small sample size, multivariate control measures were not introduced into our analytic models. Instead, we used a simple "before–after" research design and a dependent samples *t* test to assess if there were statistically significant differences comparing the arithmetic average values of the exogenous variables measures at baseline with the same measures 6 months later. All tests report the achieved *P* value for a two-tailed matched pair *t* test comparing average values at Time 1 (baseline) and to Time 2, 6 months later.

The disadvantages of this statistical analysis are that the degrees of freedom are decreased by half (increasing the standard error) and that statistical control measures are not used. On the other hand, the before–after design itself introduces significant statistical control for a number of factors (e.g., age, race, sex, education, etc.), and the results are uncomplicated.

Table 1. Patient Characteristics at Baseline and 6 Months

Characteristics	*Baseline*	*6 months*
Type 1 diabetes mellitus	8	
Type 2 diabetes mellitus	8	
Female	10	
Male	6	
Black American	8	
Caucasian	8	
Mean age (years)	41	
Oral treatment only	2	1
Insulin only	8	6
Insulin and oral treatment	6	9

RESULTS

We identified 16 of 27 patients screened who met the inclusion criteria for our study. The patient characteristics are shown in Table 1.

Mean A1C reductions at 6 months compared with baseline for the entire group were obtained as well as intergroup comparison based upon site utilization. Classification for group usage was as follows: moderate/heavy users (greater than bimonthly usage), $n = 8$; and light/never users (less than bimonthly usage), $n = 8$.

The average A1C at baseline for all 16 patients was 10.95 ± 1.45%. The average A1C at 6 months for all patients was 8.73 ± 1.84%. A1C was reduced by 2.22 percentage points in the total group ($P = 0.001$). Differences between moderate/heavy users ($n = 8$) versus light/never users ($n = 8$) of the MyCareTeam site were evaluated for intergroup differences based upon utilization of the site. A significant response was seen in moderate/heavy users compared with light/never users. Moderate/heavy users had a baseline A1C of 10.83 ± 1.27% compared with 11.08 ± 1.69% in light/never users. At 6 months moderate/heavy users' A1C was reduced to 7.68 ± 0.09% compared with 9.79 ± 1.98% in light/never users. At 6 months moderate/heavy users had a significant A1C reduction of 3.15 percentage points ($P = 0.02$) compared with a reduction in A1C of 1.28 percentage points in light/never users (difference not significant) (Fig. 2).

Other secondary end points (Table 2) were improved as well, including systolic BP, diastolic BP, total cholesterol, HDL, LDL, and TG, although the results were not significant. Mean total cholesterol for the entire group at baseline was 214 mg/dL and at 6 months was 189 mg/dL. At baseline HDL was 55 mg/dL compared with 52 mg/dL at 6 months. At baseline LDL was 134 mg/dL compared with 116 mg/dL at 6 months. The respective TG value was 123 and 114 mg/dL. Mean systolic BP at baseline was 122 mm Hg and was reduced to a mean of 116 mm Hg at 6 months. Mean diastolic BP was 72 mm Hg and was reduced to a mean of 71 mm Hg at 6 months. However, as expected, BMI had a mean increase of 2.3 kg/m^2 points over the 6-month period due to aggressive diabetes management with insulin therapy (Table 2).

DISCUSSION

Currently diabetes management is based heavily on medical nutritional therapy and pharmacotherapy. However, despite maximiz-

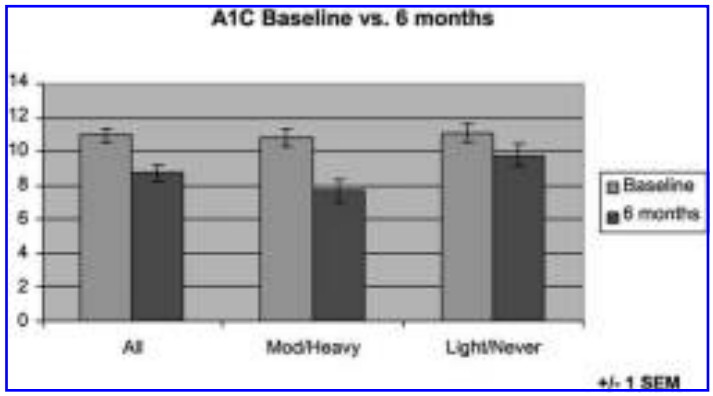

FIG. 2. Average A1C percent results at baseline versus 6 months.

Table 2. Results for Non-Glucose Parameters

End point	*Baseline*	*6 months*	P *value*
BMI (kg/m^2)	33.2	35.5	<0.05
Systolic BP (mm Hg)	122	116	NS
Diastolic BP (mm Hg)	72	71	NS
LDL-cholesterol (mg/dL)	134	116	NS
HDL-cholesterol (mg/dL)	55	52	NS
TG (mg/dL)	123	114	NS

NS, not significant.

ing these treatment modalities within the poorly controlled diabetes population, the ADA targets for glycemic control are still not being met. The failure to reach these ADA targets is multifactorial. To make significant clinical improvements in the poorly controlled diabetes population, there is a need for a modality that allows for more frequent therapeutic changes that will translate into normoglycemia. Conventional therapies allow for changes every 2–3 months; however, this has not proven to be successful. The concept of $INTV_I$ is a new concept in diabetes management. Medications that have shorter half-lives are given at greater frequencies daily in order to obtain therapeutic levels of the medication. Those medications with longer half-lives are given with lesser frequencies to obtain appropriate therapeutic blood levels. We proposed that diabetes management for the more poorly controlled patient may need a similar approach.

Those patients who sustain an A1C of >8.5%, as in our study population, have had too wide an interval for intervention. Prescribing a "shorter half-life" $INTV_I$ will translate into improved glycemic control. MyCareTeam is an Internet-based application designed to enable the healthcare provider to give weekly $INTV_I$ instead of the conventional monthly to quarterly therapeutic changes for diabetes patients. MyCareTeam fostered the capability to make frequent medical nutritional therapy and pharmacotherapy changes. Regular scheduled clinic appointments were complemented by interoffice assessments via MyCareTeam. Physician–patient contact is invaluable in the success for managing these most difficult patients, and this tool is not meant to displace the physician–patient routine office or emergent visits but to enhance them. MyCareTeam provides the tools to make necessary daily clinical assessments with weekly interventions as needed.

Our results demonstrate a significant treatment effect of web-based diabetes management. Even though our feasibility study population was small and did not include a control group, our study did show significant trends in the reductions of A1C in the moderate/heavy users (site use at least twice monthly) versus those who were light/never users of the site (less than twice monthly). The explanation for this difference could be that the moderate/heavy users were patients who were more motivated than nonusers, or that the Internet as a tool for communication with the physician was more practical than making frequent visits (bimonthly) to the physician's office. It is difficult to determine why some of our patients were more motivated to use the Internet technology than others. One possibility is that they were more motivated initially but were not guided in how to care for their diabetes and that physician–patient contact via MyCareTeam provided the guidance they needed. We do not have a way to sort out why some patients were more motivated than others to use MyCareTeam and thus improve their blood sugars from the data we collected. With the use of this Internet tool, patients are having more contact with their physician who helps educate the patient about his or her disease process. The provider spent 3–5 min per patient reviewing and commenting via MyCareTeam on the readings each time the patient transferred his or her glucose readings to MyCareTeam or new lab results were available. The patients using this system are in a type of apprenticeship with their healthcare provider. With time, the pa-

tient regains a sense of control in management of his or her diabetes and allows the individual to make appropriate dietary and medical changes with physician supervision. A larger randomized control clinical trial of the MyCareTeam application is underway at the Boston Veterans Administration Healthcare System. We expect to see true intergroup differences between those patients using MyCareTeam and those that are not.

The significant reduction in A1C seen for the moderate/heavy users compared with the light/never users is exciting and encouraging. Having a clinically designed Internet tool that emphasizes patient education and safe aggressive pharmacotherapy will be invaluable if indeed it proves to improve glycemic control significantly with subsequent reductions in morbidity and mortality in larger, longer-term clinical trials. We propose that Internet-based programs such as MyCareTeam will allow for ADA targets to be obtained using frequent $INTV_I$ in the poorly controlled diabetes population as was seen in this population of patients at Georgetown University Medical Center Endocrine Clinic.

CONCLUSIONS

If these results are confirmed, web-based disease management applications, like MyCareTeam, may prove to be the link to achieving target ADA glycemic goals in patients with poorly controlled, complicated diabetes. Having a new intervention, like MyCareTeam, as an adjunct to conventional follow-up allows for a narrower "$INTV_I$" intervention interval, which may be needed to achieve ADA target goals in the population with poorly controlled diabetes. Having the infrastructure for a care system that helps patients manage this chronic, potentially debilitating disease may prove invaluable in maintaining optimum glycemic control, thereby reducing microvascular and macrovascular disease complications. This will result in fewer hospitalizations, reduced healthcare costs, and most important a healthier population with diabetes.

We propose that a close link between the primary care provider and the patient regarding education, medication adjustments, and glucose control can occur in a more efficient way with the use of Internet communication.[19] Internet technology offers a new strategy for engaging patients with diabetes and primary care provider interaction through information exchange, emotional support, and encouraging behavioral change, as well as monitoring key treatment markers. Future large, randomized-controlled studies are needed to test the possible benefit between conventional therapy and conventional therapy supplemented by web-based care program such as MyCareTeam.

ACKNOWLEDGMENTS

We thank Alan Neustadtl, Ph.D., Associate Professor of Sociology at the University of Maryland, College Park, MD, for data review and statistical analysis. A grant from the Endocrine Fellows Foundation (Santa Monica, CA) supported this study.

REFERENCES

1. The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329:977–986.
2. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes. (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. Lancet 1998;352: 837–853.
3. Hejlesen OK, Plougmann S, Cavan DA: DiasNet—an Internet tool for communication and education in diabetes. Stud Health Technol Inform 2000;77:563–567.
4. Menzin J, Langley-Hawthorne C, Friedman M, Boulanger L, Cavanaugh R: Potential short-term economic benefits of improved glycemic control. A managed care perspective. Diabetes Care 2001;24:51–55.
5. Po YM: Telemedicine to improve patients' self-efficacy in managing diabetes. J Telemed Telecare 2000; 6:263–267.
6. Muhlhauser I, Berger M: Evidence-based patient information in diabetes. Diabet Med 2000;17:823–829.
7. Gomez EJ, del Pozo F, Hernando ME: Telemedicine for diabetes care: the DIABTel approach towards diabetes telecare. Med Inform (Lond) 1996;21:283–295.
8. Albisser AM, Harris RI, Sakkal S, Parson ID, Chao SC: Diabetes intervention in the information age. Med Inform (Lond) 1996;21:297–316.

9. Bierman E, Dietrich W, Rihl J, Standl E: Are there time and cost savings by using telemanagement for patients on intensified insulin therapy? A randomized, controlled trial. Comput Methods Programs Biomed 2002;69:137–146.
10. Chase HP, Pearson JA, Wightman C, Roberts MD, Oderberg AD, Garg SK: Modem transmission of glucose values reduces the costs and need for clinic visits. Diabetes Care 2003;26:1475–1479.
11. Winnett RA, Moore JF, Wagner JL, Hite LA, Leahy M, Neubauer TE, Walberg JC, Walker WB, Lombard D, Geller ES: Altering shoppers' supermarket purchases to fit nutritional guideline: an interactive information system. J Appl Behav Anal 1991;24:95–105.
12. Winnett RA, Anderson ES, Bickley PG, Walberg-Rankin J, Moore JF, Leahy M, Harris CE, Gerkin RE: Nutrition for a Lifetime System©: a multimedia system for altering food supermarket shoppers' purchases to meet nutritional guidelines. Comput Human Behav 1997;13:371–392.
13. Tate DF, Wing RR, Winett RA: Using Internet technology to deliver a behavioral weight loss program. JAMA 2001;285:1172–1177.
14. Prochaska JO, DiClemente CC, Velicer WF, Rossi JS: Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. Health Psychol 1993;12:399–405.
15. Marcus BH, Bock BC, Pinto BM, Forsyth LH, Roberts MB, Traficante RM: Efficacy of an individualized motivationally-tailored physical activity intervention. Ann Behav Med 1998;20:174–180.
16. Tsang MW, Mok M, Kam G, Jung M, Tang A, Chan U, Chu CM, Li I, Chan J: Improvement in diabetes control with a monitoring system based on a handheld, touch-screen electronic diary. J Telemed Telecare 2001;7:47–50.
17. Frost D, Beischer W: Telemedicine in the management of pregnancy in type 1 diabetic women. Diabetes Care 2000;23:863–864.
18. Jacobson AM, DeGroot M, Samson J: The evaluation of two measures of quality of life in patients with type 1 and type 2 diabetes mellitus. Diabetes Care 1994;17:267–274.
19. Bradley C: Diabetes treatment satisfaction questionnaire (DTSQ). In: Bradley C, ed. Handbook of Psychology and Diabetes. Chur, Switzerland: Harwood Academic Publishers, 1994:111–132.

Address reprint requests to:
Betty A. Levine, M.S.
Division Head, eHealth and Telemedicine
ISIS Center
Georgetown University Medical Center
2115 Wisconsin Avenue, NW
Box 571479
Washington, DC 20057-1479

E-mail: levineb@georgetown.edu

This article has been cited by:

1. Richard W. Grant , Jonathan S. Wald , Eric G. Poon , Jeffrey L. Schnipper , Tejal K. Gandhi , Lynn A. Volk , Blackford Middleton . 2006. Design and Implementation of a Web-Based Patient Portal Linked to an Ambulatory Care Electronic Health Record: Patient Gateway for Diabetes Collaborative Care. *Diabetes Technology & Therapeutics* **8**:5, 576-586. [Abstract] [PDF] [PDF Plus]
2. Garry Welch, Rebecca Shayne. 2006. Interactive behavioral technologies and diabetes self-management support: Recent research findings from clinical trials. *Current Diabetes Reports* **6**:2, 130. [CrossRef]