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The Effects of a Web-Based Intervention on the Physical Outcomes Associated with Diabetes Among Adults Age 60 and Older:

A Randomized Trial

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Abstract

Background—The emergence of the World Wide Web in the last decade has made it feasible for the Internet to be a vehicle for chronic disease management.

Methods—A randomized controlled trial (n = 62) testing the effects of a 6-month web-based intervention plus usual care, compared with usual care alone, among adults 60 years of age and older with diabetes. The outcomes were hemoglobin A1c (HbA1c), blood pressure, weight, cholesterol, and high-density lipoprotein (HDL) levels.

Results—A multivariate analysis of covariance controlling for all baseline outcome variables, age, gender, and number of years with diabetes showed significant (P = 0.001) reductions in HbA1c, weight, and cholesterol level and significant improvement in HDL levels in the intervention versus the control group.

Conclusions—Findings show a web-based intervention was effective in improving HbA1c, weight, cholesterol, and HDL levels at a 6-month follow-up. Future research is needed to investigate the long-term effectiveness of web-based interventions.

INTRODUCTION

Recent statistics show that 20.8 million (7%) of Americans have diabetes.[1,2] This is up 14% since 2003, and by 2050 this number will increase by 225% to approximately 45 million.[3] According to the American Diabetes Association the new numbers highlight the growing diabetes epidemic in the United States and reinforce the need for increased research so that all Americans with diabetes can have access to affordable and adequate health care. Given these staggering predictions, the potential feasibility of delivering chronic disease management interventions via the World Wide Web presents a major opportunity to provide accessible health care for

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our communities. In addition, as demographics in the United States shift toward an older population, the number of adults over the age of 65 living with diabetes will increase dramatically.[4-6] Because many older adults are limited in their ability to access clinic/office care due to such problems as physical disabilities, medical and psychiatric comorbidities, and inadequate financial resources, the development of new cost-effective methods for promoting diabetes self-management behaviors presents health care professionals with a matter of the highest priority.[7-9]

In recent years, Internet-based interventions have become available.[10] These interventions use the Internet to record, measure, monitor, manage, and deliver health care. Such technological advances have created new interactions between patient and provider that now enable patients to remotely provide personal health information to providers. Patients can download their blood glucose readings, which providers can use to evaluate the impact of a treatment (e.g., change in medication).[11] Providers, on the other hand, have the ability to communicate with their patients regarding information and feedback on the management of their disease. As a result, patients may benefit from an improved control and understanding of their disease, as well as an ability to self-monitor from home, which tends to reduce the burden of the disease.

Studies that have used some type of an Internet-based intervention (transmission of data, e-mail, accessing health-related educational information, or online support groups) have been conducted with a variety of chronic conditions, including diabetes, asthma, depression, congestive heart failure, osteoarthritis, pain, and human immunodeficiency virus.[12-19] These investigations suggest that electronic monitoring can be highly motivational for patients, and also permit more frequent contact between the patient and provider. This, in turn, enables patients to initiate more rapid changes in their management behaviors (e.g., self-monitoring, adherence) as well as changes to their treatment regimen. In addition, web technology has been reported to improve quality of life, reduce feelings of social isolation and depression, reduce at-risk health behaviors, improve confidence and skill with decision-making, and promote physical activity and weight loss.[12,15,20-22] Despite the obvious promise of web-based interventions for diabetes, the gaps in the literature are substantial, as documented in recent reviews.[23] Most studies to date have been limited to younger cohorts (under the age of 60), have combined older adults with younger adults in the analysis, or did not use a randomized design. The purpose of this study, therefore, is to investigate the impact of a 6-month web-based intervention on the physical outcomes associated with diabetes management in older adults. The specific hypothesis tested stated that the web-based intervention would improve hemoglobin A1c (HbA1c), blood pressure, weight, total cholesterol, and high-density lipoprotein (HDL) levels compared with concurrent controls.

SUBJECTS AND METHODS

Eligibility and exclusions

Criteria for inclusion were: age 60 years or older, having been diagnosed with diabetes (type 1 or type 2) for at least 1 year, living independently in the community, and oral fluency in English. Exclusions included: moderate or severe cognitive, visual, or physical impairment or the presence of severe comorbid disease (end-stage renal disease, blindness, terminal cancer). No prior computer experience was required. Individuals were eligible regardless of entry HbA1c level.

Study design

Subjects were enrolled through the University of Washington Diabetes Center, Puget Sound Health System, and local diabetes fairs held in the greater Seattle area. A total of 67 participants responded to flyers, provider referral, or letters sent to potential subjects from members of the

Washington State Diabetes Registry. Eligibility was screened by telephone prior to the baseline examination. Eligible subjects were contacted by mail and telephone and invited to attend the baseline examination, where consent was obtained. To ensure equal cell sizes, participants were randomized using a stratified two-tier strata that was based on glycosylated hemoglobin (HbA1c) level [above and below 7.5% (median cut)] and gender. Subjects were recruited to participate in one of two phases with the first phase (n = 31) beginning September 2004 and ending September 2005. The second phase started February 2005 and ended February 2006.

The study provided the computer equipment and access to the Internet if an intervention participant did not own or have access to a computer or the Internet. For subjects assigned to the intervention group who did not have access to a computer, an appointment was made by telephone for the installation of the study computer equipment, and subjects were given training to use the equipment. Follow-up examination was conducted at 6 months after the baseline examination. Personnel conducting these examinations were blinded to intervention status and were not involved in supporting the technical aspects of the intervention, or in delivering diabetes case management services. Written informed consent was obtained from all subjects. This study was approved by the Institutional Review Board at the University of Washington.

Intervention

The intervention consisted of a program designed to be delivered via the Internet to improve the participants' diabetes self-management behaviors by using behavioral and motivational strategies and cues to modify perceptions of self-efficacy and personal beliefs regarding the ability to affect the progress of the disease and change personal behavior. The patient's role in maintaining health and the importance of setting goals and using problem solving skills to overcome barriers was emphasized. Additional strategies included instruction in disease management, diet, and exercise, and the introduction of interventions to deal with the physical and emotional demands of the disease. The active intervention served as an adjunct to the usual care provided by each subject's provider. The primary care physicians of subjects in both conditions retained full responsibility and control over their patients' care.

The interaction between the study nurse and active invention participants occurred using both synchronous communication (instant messaging and chat) and asynchronous communication (e-mail and a bulletin board). In addition, participants accessed a study web site (www.diabetes-takecharge.org) to enter their blood sugar readings, exercise programs, weight changes, blood pressure, and medication data. The study nurse accessed participants' logs to monitor changes in their self-management patterns. As part of the intervention, the study nurse contacted the participant via e-mail or through instant messenger and/or chat when there were changes in blood sugar patterns that needed problem-solving to resolve. The weekly online educational discussion group treatment component was delivered by the principal investigator through a weekly online or e-mail communication using MSN Messenger software provided by Microsoft Corp (Redmond, WA). The content for these weekly educational discussion sessions was developed by using resources available from the National Institutes of Health and the American Diabetes Association. Table 1 lists the intervention resources provided as part of this study.

Control/usual care group

Participants in the control group received their standard diabetes care from their provider. No educational or training materials associated with the intervention were provided to the control group. Participants in the control group had access to educational materials/classes provided by their health provider through traditional face-to-face classroom methods and/or via the Internet.

Outcomes

The physical outcome measures were HbA1c, weight, blood pressure, HDL, and total cholesterol levels. A home visit performed by a trained research assistant/phlebotomist was done at baseline and 6 months post-intervention using a single-use home HbA1c testing kit, a blood pressure device with various-size cuffs, and a calibrated scale (Tanita Corp., Arlington Heights, IL). Total and HDL cholesterol values were collected using a Cholestech (Hayward, CA) LDX® analyzer. Demographics including age, gender, and number of years since diagnosed with diabetes were collected as part of the initial screening interview. The Self-Administered Comorbidity Questionnaire[24] was collected by interviewers at the baseline examination after informed consent had been obtained.

Sample size and power calculations

Effect size calculations for the treatmentcontrol comparison were based on a *t* test, assuming the standard deviation of change is the same for both groups using an estimated 12-month attrition rate in the 10-20% range, which was based on previous web-based intervention studies.[15,16,21,22] Sixty-two participants (including a 15% attrition rate), based on a 0.5 correlation between the pre-intervention/post-intervention scores, would provide for an intervention-control comparison of the magnitude demonstrated in the literature to detect a moderate effect size of 0.55 with an 80% power.

Statistical analysis

Univariate relations were tested with χ^2 for categorical variables and analysis of variance for continuous outcomes. A between-subjects multivariate analysis of covariance was conducted to examine the effects of the web intervention on HbA1c, weight, systolic and diastolic blood pressure, HDL, and total cholesterol levels (dependent variables), with the indicator variable of group differences, controlling for these same variables at baseline plus age, number of comorbidities, and number of years since diagnosed with diabetes.

RESULTS

The intervention and control groups did not differ with respect to baseline demographic and clinical characteristics (Tables 2 and 3). Participants with a diagnosis of either type 1 or type 2 diabetes were eligible for enrollment into the study. Eighty-seven percent of the study sample at baseline had a diagnosis of type 2 diabetes, with 13% of the sample having a diagnosis of type 1 when they entered the study. Forty-nine percent of the sample at baseline was taking insulin only, while 45% were taking both insulin and an oral agent. Six percent of the subjects at baseline managed their diabetes through diet and exercise. Three of the subjects in the treatment group did have a change in their treatment regimen during the 6-month intervention period. Of these, two subjects who were diet- and exercise-controlled at baseline were placed on an oral agent during the intervention period. The third subject had insulin added to his daily oral agent treatment.

Multivariate analysis of covariance showed significant differences between the two groups for the clinical outcomes for HbA1c, weight, systolic blood pressure, HDL, and total cholesterol levels (Table 4).

At the 6-month follow-up, the mean adjusted HbA1c level decreased in the intervention group from 7.0% to 6.4% and in the control group from 7.1% to 7.0% ($P = 0.01$; Table 3). In the intervention subgroup, participants with an HbA1c $\geq$7.5% at baseline ($n = 10$) saw their mean adjusted HbA1c level decrease from 8.7% to 7.4%. In the intervention subgroup participants with an HbA1c $\leq$7.5% at baseline ($n = 21$) saw their mean adjusted HbA1c level decrease from 6.6% to 6.0%. The median adjusted change in the intervention group for HbA1c level was a

decline of 0.60. The mean number of years since diagnoses of diabetes for the 16 participants who experienced the greatest change was 16.3 years, compared with 15 years in the group of 15 participants who experienced less change on their HbA1c level.

The mean adjusted systolic and diastolic blood pressure level decreased in the intervention group from 134/76 mm Hg to 128/70 mm Hg, while the control group remained unchanged from baseline to 6 months (130/72 mm Hg vs. 131/73 mm Hg, respectively). The respective net adjusted reductions for systolic and diastolic blood pressure in active intervention subjects were 6.8 mm Hg ($P < 0.01$) and 5.2 mm Hg ($P < 0.10$). No significant changes over the 6-month period in the control group for blood pressure were observed. An adjusted mean reduction in the total cholesterol level was seen in both the intervention and control group at 6 months, but the reduction was greater in the intervention group (11.4 mg/dL vs. 5.1 mg/dL, respectively). Adjusted mean change in HDL cholesterol level in the intervention group was 6.4 mg/dL, compared with the control group level of -1.6 mg/dL at the 6-month follow-up. For the outcome measure of weight, there was a significant ($P < 0.001$) mean adjusted reduction of 4.5 pounds in the intervention group versus a 2.5 pound increase in the control group.

Because the treatment was intensified in three of the 31 subjects (10%) randomized into the intervention group, we were concerned that the overall observed changes might be due to this intensified treatment rather than the webbased intervention. To test this, we repeated the multivariate analysis of covariance analysis excluding the three subjects whose treatment was intensified. Results remained unchanged with significant ($P < 0.05$) differences on all the clinical outcomes between the two groups.

DISCUSSION

The purpose of this study was to investigate the impact of a 6-month web-based intervention on the physical outcomes associated with diabetes management. The specific hypothesis tested was that a 6-month web-based intervention would improve HbA1c, blood pressure, weight, total cholesterol, and HDL levels compared with concurrent controls. We found that participants who received a 6-month diabetes web-based intervention did improve on their HbA1c, systolic blood pressure, weight, HDL, and total cholesterol levels compared with the control group. In addition, regardless of HbA1c level at baseline (above or below 7.5%), active treatment participants showed improvements on their HbA1c.

Our findings are generally consistent with other Internet-based studies using computers as a means of providing care for patients with diabetes who have reported high levels of patient acceptance, improved glycemic control, or both.[25-30] This project, however, differs from prior studies because it was nurse-based, the recruitment process did not target patients with only poor glycemic control, and computer experience or computer literacy was not required for eligibility. Additionally, this study also disproves the myth that seniors will not be attracted to the Internet as a way of communication. Lastly, the study utilized a more intense intervention that combines several behavioral strategies under the scope of one intervention (coaching, motivational, and social support).

This study was limited to a small sample of older adults, who were mainly Caucasian, well educated, and earned an annual income over $40,000. Future studies with larger numbers of subjects are needed to replicate these pilot findings. Additionally, this study did not look at the long-term effectiveness of the effects of the intervention. Furthermore, since this was a multicomponent intervention, it was not possible to determine which aspect of the intervention was most effective in contributing to changes in the physical outcome measures. Participants varied widely in how actively they used the website intervention components available to them. Unfortunately, this study lacked a diverse pool of participants in terms of race, socioeconomic

status, and geographic location. Only when new research studies allow for a diverse group of participants can we address the digital divide conundrum (lack of access to computer technologies due to linguistic, economic, educational, social, and geographic reasons).

Future research using nontraditional recruitment strategies such as search engine advertisements is needed. Second, accurate measurement of the amount of interaction each participant has with the web-based intervention, hereafter referred to as "dosage," is critical. Dosage determines "how much" is needed to produce confidence in attributing effects to program elements. A growing body of evidence indicates that the use of web-based interventions can improve physical outcomes for chronic disease management, but little is known about the long-term efficacy of these interventions. Additional research is also needed to determine whether web-based interventions are as effective as traditional face-to-face interventions, and how significant the short- and long-term cost benefits will be. Nevertheless, considering the physical and psychological changes that come with aging, support received through the World Wide Web may significantly benefit older adults in their ability to better manage their diabetes and, hopefully, improve the quality of their lives.

In conclusion, the Internet is a powerful medium for use by both health care professionals and people seeking access to care, information, and social support, but many questions still need to be explored. This study provides sound, substantiated evidence that web-based interventions can improve the health promotion activities and disease management of older adults with diabetes.

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Table 1

CHARACTERISTICS OF THE STUDY WEBSITE RESOURCES

1. Access to a library of articles and sites on diabetes and other health-related topics.
2. Receiving online advice, counseling, and encouragement from a nurse via e-mail.
3. Receiving tailored self-management instruction from the study nurse regarding the development of personal action plans.
4. The ability to participate in a weekly chat/discussion group with a nurse-led peer support question and answer and problem-solving forum.
5. Access an Internet bulletin board used to present the latest news in diabetes, to post diabetes management goals of participants, and to provide problem-solving suggestions to assist other study participants to better manage their diabetes, psychosocial well-being, and possible depression.
6. The ability to submit a daily log of diabetes self-management activities (blood sugar levels, medication administration, meal intake, weight, and blood pressure).

Table 2

Demographic and Baseline Clinical Characteristics of Study Participants in the Study by Group Assignment (n = 62)

	Control (n = *31*)	*Treatment* (n = *31*)	P *value*[a]
Age (years) (mean)	68.2 (6.2)	66.2 (5.7)	0.178
Years of education (mean)	15.9 (2.2)	15.8 (1.5)	0.887
Years with diabetes (mean)	17.8 (11.7)	16.1 (10.5)	0.743
Annual income (%)			
<40,000	48	47	0.297
>$40,000	52	53	
Gender (%)			
Male	52	58	0.399
Female	48	42	
Ethnicity (%)			
Caucasian	86	87	0.809
African American	10	4	
Native American	0	3	
Hispanic	0	3	
Other	4	4	
Computer experience (%)			
None	13	0	0.109
>6 months	3.4	2.6	
1 year	3.4	5.4	
1 year	80	92	
Marital status (%)			
Married	62	55	0.731
Single/divorced/widowed	38	45	

[a]Based on χ^2 test for categorical variables and a t test for continuous variables.

Table 3

Mean Baseline Clinical Characteristics of Study Participants in the Study by Group Assignment (n = 62)

	***Control* (n = *31*)**	***Treatment* (n = *31*)**	**P *value*[a]**
HbA1c (%)	7.1 (0.20)	7.1 (0.18)	0.878
Blood pressure (mm Hg)			
Systolic	132 (2.8)	132 (2.5)	0.915
Diastolic	74 (1.3)	76 (1.2)	0.396
HDL cholesterol (mg/dL)	43 (2.9)	43 (2.5)	0.887
Total cholesterol (mg/dL)	176 (6.5)	174 (5.7)	0.815
Weight (pounds)	207 (7.4)	200 (6.4)	0.441

Data are mean (standard error) values.

[a]Based on a *t* test for continuous variables.

Table 4

Analysis of Covariance Comparing Physical Outcomes for Treatment Versus Control Group at 6 Months Post-Intervention (n = 62)

	Mean (SD)						
	Baseline unadjusted	***6-month unadjusted***	***Diff score adjusted***	***95% confidence interval***	**d *effect size***	***Observed power***	**P *value***
HbA1c (%)							
Treatment (n = 31)	7.0 (1.1)	6.4 (1.2)	-0.62 (0.13)	-0.91 to -0.35	0.8	0.81	<0.01
Control (n = 31)	7.11 (0.91)	7.05 (0.99)	-0.05 (0.14)	-0.35 to 0.24			
HDL (mg/dL)							
Treatment (n = 31)	44 (17.6)	50 (15)	6.4 (2.1)	2.2 to 10.5	0.5	0.56	<0.05
Control (n = 31)	42.8 (14.8)	42 (15.7)	-0.16 (2.2)	-4.1 to 4.1			
Total cholesterol (mg/dL)							
Treatment (n = 31)	170 (44)	165 (38)	-11.4 (4.3)	-20 to -2.6	0.7	0.71	<0.05
Control (n = 31)	177 (30)	172 (37)	-5.1 (4.6)	-4.5 to 14.4			
Weight (pounds)							
Treatment (n = 31)	200 (36)	196 (35)	-4.5 (1.2)	-7.0 to -2.0	1.0	0.97	<0.001
Control (n = 31)	204 (40)	207 (42)	2.5 (1.3)	-0.05 to 5.1			
Blood pressure (mm Hg)							
Systolic							
Treatment (n = 31)	134 (15)	128 (13.2)	-6.8 (1.6)	-10.0 to -3.5	0.65	0.65	<0.01
Control (n = 31)	130 (13.5)	131 (10.2)	-0.98 (1.7)	-4.4 to 2.4			
Diastolic							
Treatment (n = 31)	76 (7.7)	70 (7.0)	-5.2 (1.2)	-7.8 to -2.6	0.35	0.36	<0.15

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	Mean (SD)						
	Baseline unadjusted	***6-month unadjusted***	***Diff score adjusted***	***95% confidence interval***	**d *effect size***	***Observed power***	**P *value***
Control (*n* = 31)	73 (7.1)	73 (7.2)	-2.5 (1.3)	-4.9 to 0.53			

Results are based on analyses of covariance obtained in the multivariate analysis of covariance controlling for baseline, age, gender, number of comorbidities, and number of years diagnosed with diabetes.