Effect of Computer-Generated Tailored Feedback on Glycemic Control in People With Diabetes in the Community

A randomized controlled trial

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OBJECTIVE—It is unknown whether computer-generated, patient-tailored feedback leads to improvements in glycemic control in people with type 2 diabetes.

RESEARCH DESIGN AND METHODS—We recruited people with type 2 diabetes aged ≥40 years with a glycated hemoglobin (A1C) ≥7%, living in Hamilton, Canada, who were enrolled in a community-based program (Diabetes Hamilton) that provided regular evidence-based information and listings of community resources designed to facilitate diabetes self-management. After completing a questionnaire, participants were randomly allocated to either receive or not receive periodic computer-generated, evidence-based feedback on the basis of their questionnaire responses and designed to facilitate improved glycemic control and diabetes self-management. The primary outcome was a change in A1C after 1 year.

RESULTS—A total of 465 participants (50% women, mean age 62 years, and mean A1C 7.83%) were randomly assigned, and 12-month A1C values were available in 96% of all participants, at which time the A1C level had decreased by an absolute amount of 0.24 and 0.15% in the intervention and control groups, respectively. The difference in A1C reduction for the intervention versus control group was 0.09% (95% CI −0.08 to 0.26; $P = 0.3$). No between-group differences in measures of quality of life, diabetes self-management behaviors, or clinical outcomes were observed.

CONCLUSIONS—Providing computer-generated tailored feedback to registrants of a generic, community-based program that supports diabetes self-management does not lead to lower A1C levels or a better quality of life than participation in the community-based program (augmented by periodic A1C testing) alone.

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D iabetes is a common chronic disease characterized by hyperglycemia that currently is estimated to affect >285 million people worldwide (1). People with diabetes are at high risk for serious chronic consequences, including retinopathy, nephropathy, blindness, cataracts, renal failure, limb amputation, cardiovascular events, and premature death. Indeed, the high prevalence and associated comorbidities cost $174 billion in the U.S. in 2007 alone (2,3). More than 90% of affected people have type 2 diabetes, and several large trials have shown that glucose-lowering strategies targeting an A1C <7% can reduce some of these health consequences (4,5). As such, most clinical practice guidelines recommend A1C measurement every 3 months with target values <7% (6,7).

Evidence that self-management education can reduce the impact of diabetes (8–11) has led to recommendations that it be implemented for all individuals with diabetes (6,7). Information and resources designed to facilitate diabetes self-management have been freely available to people with diabetes residing in the region of Hamilton, Canada, since 1999 through a free community-based program (Diabetes Hamilton). After completing a brief questionnaire focused on diabetes-related health status and behaviors, registrants (and their primary care physicians) received access to an inventory of community resources, tools to facilitate self-care, and quarterly newsletters describing evidence-based information pertaining to diabetes. As of April 2010, >4,300 individuals (~10% of the city's population with diabetes) have registered in the program and are being followed annually.

A growing body of evidence pertaining to smoking cessation, blood pressure control, and lifestyle changes suggests that the provision of tailored information that is specific to a particular individual may achieve better health outcomes than generic information alone (12–17). Whether adding such feedback improves glycemic control and quality of life in people with diabetes in the community setting is unknown and was assessed in a randomized controlled trial.

RESEARCH DESIGN AND METHODS—This open, randomized controlled trial recruited Diabetes Hamilton registrants between June 2005 and

November 2008. People aged ≥40 years with type 2 diabetes of at least 1 year duration and whose A1C was ≥7% were included. Individuals who were pregnant, institutionalized, living with another study participant, or residing outside the city of Hamilton were excluded. Participants were recruited through Diabetes Hamilton and/or through television advertisements, direct-mail campaigns, flyers in pharmacies, and physician offices and public diabetes-information sessions. Eligible consenting participants provided information regarding their demographics, diabetes-related behaviors, health status, medication use, quality of life, and a capillary blood sample for A1C measurement, which were all mailed to the project office. Participants then were randomly allocated to either receive or not receive computer-generated, evidence-based recommendations targeting an A1C <7% and other diabetes-related goals, such as blood pressure control, smoking cessation, and foot care, that were based on their measured A1C levels and other information that they provided; participants were provided with the A1C result and an interpretation of its meaning, as well as the Diabetes Hamilton resources described above. The recommendations were designed to reinforce Canadian evidence-based guidelines for the management of diabetes and were piloted in a small group of volunteers. Interactions with participants were by mail or telephone only; all written communication with participants was copied to their primary care physician. Concealed random allocation in blocks of four stratified by A1C level (A1C ≥8.5 vs. <8.5) was conducted centrally using a computer-generated algorithm. All participants signed a written informed consent, and the study was approved by the local research ethics board.

Participants in the intervention group received tailored feedback comprising *1*) up to 20 automatically generated recommendations for glycemic control and self-management on the basis of their diabetes questionnaire responses and A1C levels (Supplementary Appendix 1), *2*) a list of local resources specific to their residence, and *3*) a simple booklet to track personal diabetes-related information. Feedback was sent at baseline, and a copy of these recommendations was resent after 3 months. Six months after randomization, all participants submitted new study questionnaires and another blood sample to measure A1C, which triggered a new set of recommendations that was reinforced

3 months later. Participants in the control group were sent their A1C results with an interpretation at baseline and 6 months. All study participants submitted a final blood sample and questionnaires 12 months after randomization. All participants received regular Diabetes Hamilton newsletters and resources throughout the study.

Outcomes

The primary outcome was the change in A1C level from baseline to 12 months. A sample of capillary blood was collected at home on the Via Post Filter Paper Card (Roche) using a lancing device and mailed to the project office for central assay. A1C levels were measured by immunoturbidimetry with the Roche Tina-Quant assay on the Hitachi 917. The assay system used in the laboratory was traceable to the Diabetes Control and Complications assay result and had a precision <4.4% at all levels (18,19).

General health-related quality of life and utility was measured using the European Quality of Life–5 Dimension (EQ-5D) scale, and the U.S. value set was used to calculate health status. This

instrument has demonstrated reliability and validity and measures quality of life on five domains, with a higher score indicating better quality of life (20). The Visual Analog Scale (VAS) for health status also was used, allowing individuals to rate their perceived health status on a scale of 0–100, with 100 reflecting perfect health. The Audit of Diabetes Dependent Quality of Life (ADDQoL) scale was used to measure diabetes-specific quality of life. The ADDQoL has established reliability and validity properties, and higher scores indicate a better quality of life (21,22).

A composite score reflecting diabetes self-management behaviors was computed on the basis of information provided by participants. This score tracked 18 specific behaviors (e.g., glucose monitoring, being physically active, foot inspection) and was calculated as a count of the number of behaviors that the participant reported. A value of one was assigned for any of the 18 recommended behaviors that were reported to have been achieved; otherwise, a value of zero was assigned. This score was calculated at baseline and at 6 and 12 months (Supplementary Appendix 2).

Table 1—Baseline characteristics of study participants

	Intervention group	Control group	P
n	233	232	
Age (years)	62 ± 11	62 ± 10	0.88
≤40	1 (0.4)	0 (0)	N/A
41–65	149 (64)	132 (57)	0.12
>65	83 (36)	99 (43)	0.11
Female	114 (49)	124 (53)	0.38
White	135 (58)	150 (65)	0.1
More than a high school education	102 (44)	126 (54)	0.04
Age of diagnosis (years)	49 ± 13	50 ± 11	0.91
Diabetes duration (years)	13 ± 10	13 ± 9	0.95
BMI (kg/m^2)	34 ± 8	32 ± 7	0.02
Weight (kg)	97 ± 24	89 ± 21	0.00
Not seeing a diabetes specialist	176 (76)	177 (76)	0.85
A1C (%)	7.85 ± 0.88	7.81 ± 0.83	0.61

Data are mean ± SD or n (%). N/A, not applicable.

Table 2—Comparison of the primary outcome, A1C

	Intervention group 12 months to baseline	Control group 12 months to baseline	Difference
All	−0.24 (−0.37 to −0.12)*	−0.15 (−0.27 to −0.03)†	−0.09 (−0.26 to 0.08)
<8.5%	−0.098 (−0.22 to 0.02)	0.00055 (−0.11 to 0.11)	−0.10 (−0.26 to 0.061)
≥8.5%	−0.81 (−1.19 to −0.44)*	−0.81 (−1.17 to −0.44)*	−0.01 (−0.52 to 0.51)

Data are means (95% CI). *P < 0.001; †P < 0.01.

Statistical analysis

Sample size calculations showed that with an α level of 0.05 and an SD of the change in A1C of 1.4%, at least 206 people had to be allocated to each group to detect a difference in A1C reduction of at least 0.5% between groups with 90% power (and a difference of at least 0.4% with 80% power). All analyses were by intention to treat. Baseline characteristics were summarized as mean values, SDs, counts, and percentages and compared using t tests or χ^2 tests. The difference between the change in A1C level from baseline to 12 months in the intervention group and the change in the control group was compared using an independent-sample t test. t Tests were used to compare the change from baseline to 12 months for the ADD-QoL, EQ-5D, and the composite self-management scores.

An exploratory linear regression was conducted to determine whether between-group differences in baseline A1C, education, ethnicity, age, sex, and diabetes duration confounded the effect of the intervention on the primary outcome. The proportions of individuals who reduced their A1C by 0.3, 0.5, or 0.7% at 12 months were calculated. Odds ratios for these three proportions were estimated through logistic regression, adjusting for baseline A1C, education, ethnicity, age, sex, and diabetes duration. In a post hoc analysis to investigate whether there were changes in process behaviors (dependent variables), such as seeking primary care, oral medications, physical activity, glucose monitoring, and hospitalizations over time, a generalized estimating equation was used in which the presence or absence of the behavior was regressed onto the randomized group, time, and the group-by-time interaction (independent variables), using a logistic link. A nonsignificant interaction was taken to indicate that there was not substantial evidence that the two groups differed in the way their behaviors changed over time. In the event that the interaction was not significant, it was removed from the model. All statistical analyses were conducted using R statistical software (version 2.4) (23).

RESULTS—Four hundred and sixty-five participants were recruited and randomly assigned for the trial, with 233 assigned to the intervention group and 232 to the control group. More than 96% of the participants in each group completed the study. Results of participants' enrollment and flow in the study are shown in Supplementary Fig. 1.

Participant characteristics

As shown in Table 1, the mean ± SD age of participants was 62 ± 11 years and 50% were female. At randomization, intervention-group participants were slightly heavier than control-group participants, with a BMI of 34 ± 8 kg/m² and 32 ± 7 kg/m², respectively (P = 0.02), and intervention-group participants were slightly less likely to have had more than a high school education (P = 0.04). The mean ± SD baseline A1C levels in the intervention and control groups were similar at 7.85 ± 0.88% and 7.81 ± 0.83%, respectively (P = 0.61).

Effect on change in A1C

As shown in Table 2, by 12 months, the A1C had decreased by an absolute amount of 0.24% (95% CI −0.37 to −0.12; P < 0.001) and 0.15% (−0.27 to −0.03; P = 0.01) in the intervention and control groups, respectively. However, as noted in Table 2, the change in A1C did not differ significantly between the two groups (between-group difference −0.09% [95% CI −0.26 to 0.08]; P = 0.3). The effect of the intervention was unchanged after adjusting for baseline A1C, age, education, BMI, and diabetes duration in a multiple regression analysis, and similar effects were seen within the two randomized strata of baseline A1C (<8.5 vs. ≥8.5%). There also was no difference in the likelihood of achieving a 0.3, 0.5, or 0.7% reduction in A1C, either before or after adjusting for baseline A1C, education, ethnicity, age, sex, and diabetes duration (Table 3).

Effect of possible cointervention

The possibility that postrandomization changes in the behavior or management of participants could have attenuated the effect of the intervention was explored by examining between-group changes in 1) health care provider visits, 2) use of new oral medications and/or insulin, 3) self-reported physical activity, 4) frequency of glucose self-monitoring, or 5) hospitalization. Regression analysis did not demonstrate differences between the two groups in the use of services, nor was there evidence of significant change in the use of services over time.

Quality of life, diabetes self-management, and clinical outcomes

Both groups improved their EQ-5D scores, VAS scores, and ADDQoL scores by the end of the study. However, the

Table 3—*Proportion of participants obtaining 0.3, 0.5, and 0.7% reductions in A1C and 95% CIs*

Outcome	Intervention group			Control group			Odds ratio (95% CI) at both 6 and 12 months		Adjusted odds ratios (95% CI) at both 6 and 12 months*	
	6 months	12 months	6 and 12 months	6 months	12 months	6 and 12 months	Estimate	P	Estimate	P
A1C drop of ≥0.3	81 (37)	101 (46)	59 (27)	73 (33)	84 (38)	50 (23)	1.26 (0.82–1.95)	0.29	1.16 (0.72–1.86)	0.55
A1C drop of ≥0.5	66 (30)	89 (40)	49 (22)	60 (27)	66 (30)	37 (17)	1.44 (0.89–2.31)	0.14	1.32 (0.78–2.24)	0.30
A1C drop of ≥0.7	39 (18)	60 (27)	24 (11)	40 (18)	49 (22)	27 (12)	0.88 (0.49–1.59)	0.68	0.70 (0.36–1.38)	0.31

Data are counts (%), unless otherwise indicated. *Adjusted for baseline A1C, education, ethnicity, age, sex, and diabetes duration.

changes did not differ significantly between the two groups (Table 4). Likewise, a composite measure reflecting diabetes self-management behaviors improved by a similar amount in both groups during the study period (−0.02 [95% CI −0.51 to 0.47]; $P = 0.95$) (Table 4). The incidence of clinical outcomes, including hospitalization, amputations, foot ulcer treatment, laser therapy, cataract surgery, heart attacks, strokes, and kidney failure were similar in both groups during the trial.

CONCLUSIONS—This trial tested the efficacy of tailored feedback on glycemic control for individuals with type 2 diabetes in the community. The findings from the study demonstrated an improvement in glycemic control in both the control and intervention groups but a nonsignificant difference between groups at 12 months. The study findings were not explained by baseline differences or postrandomization differences.

There are several strengths to the study. First, the randomized controlled study design minimized bias and confounders. Second, the study had a large sample size of 465 participants who were followed for 1 year. Third, follow-up was very high, with a 96% completion rate of participants from the community setting. Finally, the study was completed in the community, reflecting the relevance and reality of diabetes management in a nonclinical or hospital setting.

As with any educational, behavioral-change intervention, there is a risk for cointervention. First, participants and their primary care physician knew of their allocated group. It is therefore possible that participants who did not receive tailored recommendations (control group), along with their doctor, initiated extra changes to improve diabetes control, such as medication initiation or modification. Although such an effect was not observed in an exploratory analysis of postrandomization changes, unmeasured cointerventions may have been instituted. Second, participants in both groups were voluntary registrants in a community-based diabetes program. Any incremental benefit of the intervention studied in this trial may have been insufficient to surpass the effect of the community-based program alone. Third, A1C testing and reporting was provided to the control group, which may not reflect a subject's usual or routine care. The receipt of an A1C level, in addition to the community program resources, such as newsletters and the inventory of community resources, may have led to the seeking of additional information, education, and support by control-group participants to improve glycemic control. Fourth, study participants' self-reported diabetes information was not objectively confirmed. Finally, the intervention mainly comprised mail- and telephone-based interactions and did not include systematic, intensive, real-time interactions of a clinical or advisory nature by telephone, through a website, or face-to-face visits. The addition of such real-time interactions and coordination of care with health care providers has been demonstrated to have a greater effect on both A1C, quality of life, and rates of hypoglycemia (24,25). However, such an approach would have represented an individually focused, provider-driven intervention rather than a community-based, patient-driven intervention.

The literature suggests that diabetes care can be improved by providing focused information and care reminders directly to patients (12). Likewise, tailored feedback interventions geared toward patients directly in clinical or work settings were found to be effective when implemented with other interventions, such as telephone and face-to-face contact (10–15). However, our study using printed tailored feedback via mail suggested that such an approach is insufficient to significantly change A1C or quality of life in individuals with diabetes in the community setting who are exposed to information and resources offered by a community-based support program.

Diabetes is a growing public health problem that requires evidence-based community approaches. In this study, tailored recommendations were provided to 233 individuals living with diabetes in the community, along with an inventory of community resources, tools to facilitate self-care, quarterly newsletters describing evidence-based information pertaining to diabetes, feedback support, and reminder prompts. This study showed that a quarterly community-based intervention providing computer-generated recommendations is insufficient to significantly change A1C levels. Future research involving community-based approaches may include promoting community awareness of diabetes, promoting self-efficacy and self-management, promoting greater interaction between individuals and their diabetes care providers, and reducing barriers to adopting healthy lifestyles.

Table 4—Baseline and 12-month results for quality of life and diabetes management behaviors

Outcome	Intervention group		Control group			
	Baseline	12 months	Baseline	12 months	Difference	P
EQ-5D	0.72 (0.69–0.75)	0.74 (0.71–0.77)	0.75 (0.72–0.77)	0.75 (0.72–0.77)	−0.01 (−0.05 to 0.03)	0.64
EQ-5D VAS	64.6 (62.4–66.8)	68.1 (65.9–70.4)	67.0 (64.5–69.5)	65.4 (63.0–67.7)	1.15 (−2.27 to 4.56)	0.51
ADDQoL	−3.86 (−4.11 to −3.60)	−3.75 (−4.01 to −3.49)	−3.80 (−4.02 to −3.58)	−3.58 (−3.81 to −3.36)	−0.16 (−0.51 to 0.18)	0.36
Composite score	8.31 (7.98–8.64)	11.3 (10.9–11.6)	8.13 (7.82–8.44)	11.3 (11.0–11.7)	−0.02 (−0.51 to 0.47)	0.95

Data are means (95% CI). The EQ-5D scale scores range from 1 (optimal health) to −0.11 (worse than being dead), which indicates poor quality of life. The EQ-5D VAS, 0 reflects poor overall quality of life and 100 reflects optimal quality of life. The ADDQoL reflects the average weighted impact score only. ADDQoL scores range from −9 to 3, with higher scores reflecting a better diabetes-related quality of life. Composite score has a maximum score (optimal diabetes management behaviors), which is 17 at baseline and 18 at both 6 and 12 months.

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