Changes in Diabetes Self-Care Behaviors Make a Difference in Glycemic Control

The Diabetes Stages of Change (DiSC) study

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OBJECTIVE — This study compared diabetes Treatment As Usual (TAU) with Pathways To Change (PTC), an intervention developed from the Transtheoretical Model of Change (TTM), to determine whether the PTC intervention would result in greater readiness to change, greater increases in self-care, and improved diabetes control.

RESEARCH DESIGN AND METHODS — Participants were stratified by diabetes treatment and randomized to treatment with PTC or TAU as well as being randomized regarding receipt of free blood testing strips. The PTC consisted of stage-matched personalized assessment reports, self-help manuals, newsletters, and individual phone counseling designed to improve readiness for self-monitoring of blood glucose (SMBG), healthy eating, and/or smoking cessation. A total of 1,029 individuals with type 1 and type 2 diabetes who were in one of three pre-action stages for either SMBG, healthy eating, or smoking were recruited.

RESULTS — For the SMBG intervention, 43.4% of those receiving PTC plus strips moved to an action stage, as well as 30.5% of those receiving PTC alone, 27.0% of those receiving TAU plus strips, and 18.4% of those receiving TAU alone ($P < 0.001$). For the healthy eating intervention, more participants who received PTC than TAU (32.5 vs. 25.8%) moved to action or maintenance ($P < 0.001$). For the smoking intervention, more participants receiving PTC (24.3%) than TAU (13.4%) moved to an action stage ($P < 0.03$). In intention-to-treat (ITT) analysis of those receiving the SMBG intervention, PTC resulted in a greater reduction of HbA_{1c} than TAU, but this did not reach statistical significance. However, in those who moved to an action stage for the SMBG and healthy eating interventions, HbA_{1c} was significantly reduced ($P < 0$ 0.001). Individuals who received the healthy eating intervention decreased their percentage of calories from fat to a greater extent (35.2 vs. 36.1%, $P = 0.004$), increased servings of fruit per day (1.89 vs. 1.68, $P = 0.016$), and increased vegetable servings (2.24 vs. 2.06, $P = 0.011$) but did not decrease weight. However, weight loss for individuals who received the healthy eating intervention and who increased SMBG frequency as recommended was significantly greater, with a 0.26-kg loss in those who remained in a pre-action SMBG stage but a 1.78-kg loss in those performed SMBG as recommended ($P \leq 0.01$).

CONCLUSIONS — This study demonstrates that this intervention has the potential of positively impacting the health of broad populations of individuals with diabetes, not just the minority who are ready for change.

Diabetes Care **26:732–737, 2003**

Diabetes self-management, including self-monitoring of blood glucose (SMBG) and making healthy food and lifestyle choices, is complex and demanding. The Diabetes Control and Complications Trial (DCCT) and the U.K. Prospective Diabetes Study (UKPDS) demonstrated the beneficial impact of improved glycemic control on the long-term complications of type 1 and type 2 diabetes (1,2). However, translating the glycemic reductions achieved in these pivotal trials to clinical settings remains difficult. Developing effective and efficient strategies to promote self-management is important to this process.

Although effective, most current diabetes education programs use approaches that are suited to individuals who are ready to change and, therefore, reach only a minority of those in need (3). In Southern Ontario, Canada, despite a universal health care system, only 25% of patients with diabetes are estimated to have attended a Diabetes Education Program (4). Recently, the Transtheoretical Model of Change (TTM) has been applied to health behavior change interventions using a computerized system, Pathways to Change (PTC), which provides self-care

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Received for publication 12 June 2002 and accepted in revised form 14 November 2002.

H.J. and B.Z. have participated on an Advisory Board of LifeScan and have received honoraria from LifeScan for participation in symposia and workshops. M.V. has received grant/research support from LifeScan. L.E. is a member of the LifeScan Educational Institute Advisory Panel for LifeScan Canada, has received honoraria for her participation in this Advisory Panel, and has been hired as a consultant for LifeScan Canada on numerous projects. J.S.R. has received an honorarium for a speaking engagement from LifeScan. L.R. has received honoraria for speaking engagements and research and educational grants from LifeScan. H.J., B.Z., M.V., L.E., J.S.R, and S.R.R. received funding through an unrestricted grant for completion of the Diabetes Stages of Change (DiSC) study from LifeScan, a Johnson and Johnson Company. Successful results of this project may lead to the development of products by LifeScan, which may result in royalties for J.S.R and S.R.R. as contributing authors and developers of such products, as well as their employer, the University of Rhode Island.

Abbreviations: DCCT, Diabetes Control and Complications Trial; ITT, intention-to-treat; PTC, Pathways To Change; SMBG, self-monitoring of blood glucose; TAU, Treatment As Usual; TTM, Transtheoretical Model of Change; UKPDS, U.K. Prospective Diabetes Study.

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

interventions delivered by phone and mail, with or without personal contact. Such interventions have the potential to reach large numbers of individuals who do not participate in current health care systems.

The TTM posits that people pass through five specific stages when changing health behaviors. Pre-action stages include 'precontemplation,' in which the individual is not intending to change in the foreseeable future, usually measured as the next 6 months; 'contemplation,' in which the individual is not prepared to change his/her behavior at present but is intending to take action within the next 6 months; and 'preparation,' when the individual is actively considering changing his/her behavior in the immediate future. Action stages include 'action,' in which the individual has actually made an overt behavior change in the recent past but the changes are not well established (i.e., within 6 months of change); and 'maintenance,' when the individual has changed his/her behavior and is working to sustain the overt change after the first 6 months (5). TTM interventions have been developed and tested for a variety of populations and behaviors (6–8). Individualized interactive interventions based on TTM constructs have been shown to be more effective than more traditional approaches, which focus on the individual who is ready to change (8).

Diabetes self-management is fundamentally different from many health behaviors studied, such as smoking or use of sunscreen. The behavior changes required are more complex, numerous, expensive, and restrictive. We report on the first randomized, prospective trial evaluating an intervention based on the principles of the TTM and targeted at three diabetes self-care behaviors: frequency of SMBG, healthy eating, and smoking cessation. The PTC intervention includes stage-based personal feedback reports, self-help manuals and newsletters delivered by mail, and personal counseling via telephone. It does not require face-to-face contact with the individual.

We hypothesized that, compared with Treatment As Usual (TAU), patients receiving the PTC intervention will demonstrate more forward movement in stage of readiness for SMBG, healthy eating, and smoking cessation, increased frequency of SMBG as assessed by memory meters, decreased intake of dietary fat, improved metabolic control as assessed by HbA_{1c}, and greater weight loss. We also evaluated the impact of receiving free glucose test strips on SMBG frequency.

RESEARCH DESIGN AND METHODS

Study design

The complete methodology for this study is described elsewhere (9). Briefly, a total of 1,029 individuals with type 1 or type 2 diabetes were recruited for this 12-month study, approved by the Research Ethics Boards of the University of Toronto and Dalhousie University. Two thirds of the cohort were recruited from Southern Ontario, Canada and one third of the subjects were recruited from Nova Scotia. The aim was to recruit individuals from the general diabetes population who were not engaging in optimal self-care practices. Participants were considered as being in a pre-action stage if they performed SMBG fewer than four times per day if treated with insulin or fewer than two times per day if treated with oral antihyperglycemic agents alone, and/or if they had a BMI >27 kg/m^2, and/or if they smoked cigarettes. Patients were ineligible for participation in the study if they were on diet therapy alone, if they could not respond to the materials written in English, if they required more than usual care because of their health status (e.g., were pregnant or on dialysis), or if they had no telephone. Participants were recruited from posters in local family practices, diabetes education centers, newspaper ads, and Canadian Diabetes Association chapter activities.

This study was a randomized split-plot design with two randomized between-subject factors: treatment (PTC versus TAU) and strips (free strips versus no strips) and one within-subject factor (pre- versus post-study). Because treatment recommendations are different, participants were stratified according to whether or not they took insulin or oral agents alone and were then randomized into treatment or strips conditions.

Participants received a PTC intervention for each of the behaviors appropriate for them. The PTC intervention is fully described elsewhere (9). In summary, PTC is an integrated, multicomponent intervention program that provides monthly mail or telephone contact for 12 months. The components of the intervention are based on the individual's current stage of change, as well as stage-matched processes and principles of change. A handbook providing general diabetes information and an introduction to the TTM was mailed to PTC participants after recruitment. Individual stage was assessed using quarterly assessment surveys. Survey responses were used to generate a personal report from a computer-based "expert system" (10–16), which provides personalized feedback for each self-care behavior. This report is stage-matched and individualized to provide participants with the strategies most useful in moving toward action and maintenance. Counselors conducted telephone calls 1 month after the personal report to answer questions, provide tips on behavior change, and facilitate personal goal-setting. Seven newsletters were mailed approximately every other month so that monthly contact was made for 12 months.

TAU involved regular family physician or endocrinology visits and/or diabetes education sessions as prescribed. Education and physician care is covered by provincial health plans. No attempt was made to influence medical management in either group.

All subjects with BMI >27 kg/m^2 (a measure of obesity) were enrolled in the healthy eating intervention, but only those reporting being in a pre-action stage for healthy eating (diet $>30\%$ fat, $n = 445$) were used for the analyses reported herein.

Assessment measures

The protocol required participants to visit the diabetes center twice during the study, for baseline and end-of-study assessments. Participants were asked to use a memory blood glucose meter (LifeScan Profile; LifeScan, Milpitas, California) and phone modem to send blood glucose results to a data center (Enact, Mountain View, California) for the duration of the study. These were distributed free of charge to all participants. Patients' blood glucose data were used solely for outcome assessment and not as an intervention.

Stage of change was assessed through questions addressing intention to change and current behavior, as described in Table 1. A specific action criterion was used to drive the staging algorithms. Participants were informed of this criterion before intention was assessed. TTM measures were developed using explor-

Table 1—*PTC staging measures*

Component	Healthy eating	SMBG	Smoking
Criterion for action stage	Consuming diet with <30% fat	Testing frequency ≥four times daily for insulin users or ≥two times daily if on oral agents	Smoking cessation
Stage of change measures	• A single-item staging algorithm based on intention alone • Five behavioral items regarding eating habits • A follow-up staging question	• Self-reported testing frequency • A single-item staging algorithm based on intention alone	• Smoking history • Current smoking status • Intention to quit • History of quit attempts

atory and confirmatory analyses, structural equation modeling, and split-half cross-validation (15).

HbA_{1c} was measured from a venous blood sample using an immunoturbidometric method. Height and weight were measured and BMI was calculated (kg/m^2). Dietary intake was measured using a validated food frequency instrument, the NCI Block (17,18). For PTC participants, the staging measures were obtained at baseline and at 3, 6, 9, and 12 months. For TAU participants, there was no contact from the initial assessment until the 12-month end-of-study assessment, except for reminders to download the data from the blood glucose meter, if required. Health care utilization information (visits with family physician, medications used, diabetes education received) was also collected at baseline and at 12 months.

Data analysis

Participants who did not complete the study were coded as remaining in pre-action for the intention-to-treat (ITT) analyses. The main comparisons were between the proportion of participants in PTC versus TAU, and free strips versus no free strips for the SMBG intervention, across the stages (pre-action versus action and maintenance stages) at end of study. Differences in proportions were tested using χ^2 analyses. If main effects of both treatment and strips were significant for the self-testing risk, the interaction was analyzed by comparing the outcome for each of the four groups (TAU alone, TAU plus strips, PTC alone, and PTC plus strips) using χ^2 analysis.

Outcomes for glycemic control (HbA_{1c}), weight, meter memory data, and eating behavior were analyzed using repeated-measures ANOVA. The SMBG frequency data per memory meter was coded to obtain an average weekly blood glucose level for weeks 5–8 and 49–52 of the study. Data from weeks 1–4 were not used to minimize any temporary increase in SMBG frequency associated with starting the study.

RESULTS — Participants' baseline characteristics are shown in Table 2. There were no significant differences between groups. The 1,029 participants received one or more interventions, depending on their current stage for each behavior. A total of 860 participants were enrolled for SMBG; 77.7% completed the entire year of the study. A total of 445 participants were in pre-action for healthy eating, and 168 participants were in pre-action for smoking; completion rates were 81.2 and 80.4%, respectively. Participants who did not complete the entire 12 months of the study did not have different baseline demographic characteristics from those who did complete the study (data not shown). A total of 58.2% of participants were enrolled for two behaviors (89% of these for both SMBG and healthy eating) and 8.2% of participants were enrolled for three behaviors.

Table 2—*Sample characteristics*

	PTC		TAU		
Factor	Strips	No strips	Strips	No strips	*P*
Age	54.58	55.12	54.86	54.60	0.947
Duration of diabetes	10.09	10.43	11.15	10.24	0.523
No. insulin-treated	87	80	97	86	0.636
No. using oral agents	173	170	172	164	0.962
Hb A_{1c}	0.0849	0.0843	0.0861	0.0848	0.662
BMI	31.98	32.22	31.43	31.59	0.509
Risk: healthy eating	187	179	183	164	0.637
Risk: SMBG less than recommended	219	194	211	179	0.190
Risk: smoking	35	34	41	38	0.847
Sex					0.491
Women	124	109	132	125	47.6%
Men	136	141	137	125	52.4%

Table 3—*Stage at end of study: PTC intervention compared with TAU in three self-care behaviors*

	Pre-action	Action	Maintenance	
SMBG				
TAU	81.6%	10.9%	7.5%	$\chi^2 = 66.72$
TAU + strips	73.0%	17.3%	9.7%	$P < 0.001$
PTC	69.6%	12.1%	18.4%	$n = 860$
PTC + strips	56.6%	10.2%	33.2%	
Healthy eating				
TAU	74.2%	25.8%	0%	$\chi^2 = 26.52$
PTC	67.5%	21.1%	11.4%	$P < 0.001$
				$n = 445$
Smoking				
TAU	88.4%	11.6%	0%	$\chi^2 = 7.01$
PTC	76.7%	17.8%	5.5%	$P = 0.03$
				$n = 168$

At baseline, 100% of participants were in pre-action.

Stage of change

We hypothesized that significantly more participants in the PTC intervention than the TAU intervention would shift from pre-action to an action stage (either action or maintenance). In view of this directional hypothesis and the fact that all participants were in a pre-action stage at baseline and could not regress further, a one-tailed statistical test was used. ITT analyses comparing treatment groups for each self-care behavior are presented in Table 3.

SMBG. There was a significant treatment effect for PTC versus TAU ($\chi^2 = 45.42$, $P < 0.001$) and for whether or not free testing strips were provided ($\chi^2 = 13.13$, $P < 0.002$). Table 3 shows the data examining the four treatment groups (TAU alone, TAU plus strips, PTC alone, PTC plus strips); 10.9% of the TAU group moved to action and 7.5% moved to maintenance, whereas of those receiving testing strips alone, 17.3% moved to action and 9.7% moved to maintenance. Of those receiving PTC alone, 12.1% moved to action and 18.4% moved to maintenance. When PTC and strips were combined, 10.2% of participants moved to action and 33.2% moved to maintenance ($P < 0.001$).

Healthy eating. The χ^2 analysis based on the ITT sample (445 in pre-action at baseline) demonstrated that PTC was associated with more movement to action/maintenance than TAU ($P < 0.001$). The superiority of PTC can be seen in the larger proportion of participants who are in maintenance at end of study (11.4%) compared with TAU (0%) ($\chi^2 = 26.52$, $P < 0.001$).

Smoking. There were significantly more PTC than TAU patients who quit smoking (17.8% in action and 5.5% in maintenance vs. 11.6% in action and 0% in maintenance, respectively) in the ITT analysis for the 168 enrolled smokers ($\chi^2 = 7.01$, $P = 0.02$).

Changes in self-care outcomes

Differences in favor of PTC are seen for SMBG frequency in those providing end-of-study data ($P = 0.002$). Only PTC participants significantly increased SMBG frequency (from 1.4 to 1.6 tests per day) as measured by downloaded meter memory data, compared with a slight decrease in the TAU group (1.46 to 1.41 tests per day, $P < 0.002$). Likewise, the results for the NCI Block Food Frequency Questionnaire indicated that PTC participants, relative to TAU participants, reported lower percentage of calories from fat (35.24 vs. 36.1%, $P < 0.004$) and higher daily vegetable (2.24 vs. 2.06, $P < 0.011$) and fruit servings (1.89 vs. 1.68, $P < 0.01$).

Changes in health care utilization indicators of self-care

Participants' visits to family physicians remained consistent: 4.61 visits for the TAU group and 4.75 visits for the PTC group during the study year; 4.87 and 4.74 visits, respectively, for the prior year (NS). Participants in both groups changed the dose or frequency of oral agent therapy equally during the study year (84.6% of the PTC group versus 83.3% of the TAU group). Although 22% of PTC insulin-using participants changed to an insulin analog, as compared with 13% of the TAU group, this did not reach significance ($P = 0.082$). Both PTC and TAU participants increased the frequency of injections (from 2.45 to 2.76 per day in the PTC group, from 2.32 to 2.54 in the TAU group; pre- versus post-$F = 32.36$, $P < 0.001$; interaction $F = 0.96$, NS). Finally, more patients in the PTC group participated in diabetes education programs than patients in the TAU group (47.7 and 37.7%, respectively; $P = 0.002$).

Impact of self-care change

In an ITT analysis, a significant reduction in HbA_{1c} resulted only for those participants who reached action or maintenance stages over the course of the study. End-of-study HbA_{1c} for the SMBG intervention was 7.78% for those who reached an action stage, compared with 8.30% in those who stayed in pre-action ($P < 0.003$). In the healthy eating group, HbA_{1c} was 7.83% for those in action but remained at 8.38% for those in pre-action ($P < 0.001$). Increased SMBG accounted for 3% of the variance in end-of-study HbA_{1c} level in the non–insulin-treated group ($P < 0.01$) and 7% in the insulin-treated group ($P < 0.01$).

In the healthy eating group, weight reduction was greater for the PTC participants who were in an action stage at end-of-study as compared with those in pre-action, but this did not reach significance. Weight loss for those remaining in pre-action was 0.65 kg, compared with 1.38 kg in patients moving to action (NS). However, weight loss for those enrolled in both SMBG and healthy eating interventions, and who increased SMBG frequency as recommended, was significantly greater than those who remained in a pre-action stage (1.78- versus 0.26-kg loss, $P < 0.01$).

CONCLUSIONS

These data suggest that the PTC intervention is significantly better than TAU in helping individuals move into action stages of critical diabetes self-care behaviors. The PTC intervention was successful at helping more people engage in SMBG, make healthy low-fat food choices, and stop smoking. Patients who changed SMBG and healthy eating behavior had a

significant improvement in metabolic control, whether they used insulin or oral agents. Results for smoking cessation suggest that PTC is superior to TAU, but the confidence in these findings is limited by small sample size.

The importance of self-care behavior change interventions for improved glycemic control is supported by recent studies.

For example, an intensive individualized behavioral change program for individuals with impaired glucose tolerance was successful in reducing the incidence of diabetes (19). However, individual interventions are labor-intensive and time-consuming to deliver to the large numbers of patients with diabetes. In contrast to face-to-face diabetes education efforts, the PTC interventions are efficient and have a broad reach. Intervention was accomplished by mailing individualized written material, with follow-up telephone counseling but no clinic visits. This program provides stage-matched as well as individually tailored feedback to participants' personal survey responses. The system provides individualized normative and/or ipsative feedback, which allows even small positive steps to be reinforced. As implemented, this intervention may positively impact the health of broad populations of individuals, not just those who attend diabetes clinics, and augment the impact of diabetes care/education services.

Although SMBG is accepted as critical for patients using insulin, its role in patients with type 2 diabetes is less clear. In a cross-sectional sample of patients with type 2 diabetes from the National Health and Nutrition Examination Survey (NHANES), the frequency of SMBG was not found to be related to glycemic control as measured by HbA_{1c} (20). In our study, patients with type 2 diabetes taking oral agents who performed SMBG more frequently did demonstrate a significant reduction in HbA_{1c}, which supports other recent findings (21). The DiSC study data are unique because of the prospective nature of collection. Furthermore, the participants of this study were encouraged to learn more about using blood glucose information. Those that tested more had a significant reduction of HbA_{1c} regardless of treatment used.

This study also demonstrated the potentiating effects of access to free testing strips on both PTC and TAU interventions. Access to supplies does impact frequency of SMBG, and testing frequency improves HbA_{1c}. These findings support long-term benefit of financial coverage of testing supplies by third-party payers.

Future research is required to isolate the impact of each component of the PTC. Because the comparison group in this study was TAU, we are unable to state definitely whether the theory-specific aspects of PTC, or general aspects of behavioral intervention, were responsible for the outcomes. Future research should compare the efficacy of a stage approach with a nonstaged frequent contact approach in the context of complex multiple and concurrent self-care behaviors of chronic illness.

The PTC intervention has the capacity to deliver effective interventions to a large number of people. By helping people through the precontemplation and contemplation stages in a timely fashion, we may be able to redirect our efforts to diabetes care and education strategies that will have a positive impact on the prevention of long-term complications of diabetes, reducing the subsequent human and health care costs. Clearly, this study supports a new, innovative approach to this major health problem.

Acknowledgments— This research was supported by an unrestricted grant from LifeScan, a Johnson and Johnson Company. Pathways to Change (PTC) is a registered trademark of LifeScan, a Johnson and Johnson Company.

We thank Wanda Firth, Celia Fredericks, Lewinda Knowles, Lea Lehman, Hilary Ross, and Mildred Thompson for their valuable contributions to the DiSC study.

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