Integrating Medical Management With Diabetes Self-Management Training

A randomized control trial of the Diabetes Outpatient Intensive Treatment program

William H. Polonsky, PhD, CDE[1]
Jay Earles, PsyD[2]
Susan Smith, MSN, BC-ADM[2]
Donna J. Pease, ANP/GNP, CDE[2]
Mary Macmillan, BSC, BCOP[2]
Reed Christensen, MD[2]
Thomas Taylor, MD[2]
Judy Dickert, MD[3]
Richard A. Jackson[4]

OBJECTIVE — This study evaluated the Diabetes Outpatient Intensive Treatment (DOIT) program, a multiday group education and skills training experience combined with daily medical management, followed by case management over 6 months. Using a randomized control design, the study explored how DOIT affected glycemic control and self-care behaviors over a short term. The impact of two additional factors on clinical outcomes were also examined (frequency of case management contacts and whether or not insulin was started during the program).

RESEARCH DESIGN AND METHODS — Patients with type 1 and type 2 diabetes in poor glycemic control (A1c >8.5%) were randomly assigned to DOIT or a second condition, entitled EDUPOST, which was standard diabetes care with the addition of quarterly educational mailings. A total of 167 patients (78 EDUPOST, 89 DOIT) completed all baseline measures, including A1c and a questionnaire assessing diabetes-related self-care behaviors. At 6 months, 117 patients (52 EDUPOST, 65 DOIT) returned to complete a follow-up A1c and the identical self-care questionnaire.

RESULTS — At follow-up, DOIT evidenced a significantly greater drop in A1c than EDUPOST. DOIT patients also reported significantly more frequent blood glucose monitoring and greater attention to carbohydrate and fat contents (ACFC) of food compared with EDUPOST patients. An increase in ACFC over the 6-month period was associated with improved glycemic control among DOIT patients. Also, the frequency of nurse case manager follow-up contacts was positively linked to better A1c outcomes. The addition of insulin did not appear to be a significant contributor to glycemic change.

CONCLUSIONS — DOIT appears to be effective in promoting better diabetes care and positively influencing glycemia and diabetes-related self-care behaviors. However, it demands significant time, commitment, and careful coordination with many health care professionals. The role of the nurse case manager in providing ongoing follow-up contact seems important.

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From the [1]Department of Psychiatry, University of California, San Diego, California; the [2]Tripler Army Medical Center, Honolulu, Hawaii; the [3]Pearl Harbor Naval Medical Clinic, Honolulu, Hawaii; and the [4]Joslin Diabetes Center and Harvard Medical School, Boston, Massachusetts.

Address correspondence and reprint requests to Richard A. Jackson, MD, Joslin Diabetes Center, 1 Joslin Place, Boston, MA 02215. E-mail: richard.jackson@joslin.harvard.edu

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Abbreviations: ACFC, attention to carbohydrate and fat contents; BGM, blood glucose monitoring; DOIT, Diabetes Outpatient Intensive Treatment; TAMC, Tripler Army Medical Center.

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

Day-to-day clinical care in diabetes is driven by the understanding that long-term complications can be delayed and/or prevented by improving metabolic control early in the disease course (1–6). Appropriate medical management is a critical intervention for success but may not be sufficient by itself over the long term. Due to the nature of diabetes, ongoing self-care is also essential, and so efforts must be made to help the patient become knowledgeable about his or her disease, skilled in self-management, and enthused about pursuing effective self-care. Structured diabetes self-management training has been shown to be of value in each of these areas (7), but it is typically separated in time and place from medical management. This can be problematic, especially when different or even contradictory recommendations about diabetes and diabetes care are presented by the various health care providers.

As a first step toward addressing this issue, clinicians at the Joslin Diabetes Center developed the Diabetes Outpatient Intensive Treatment (DOIT) program, an interactive, 3.5-day group education and skills training experience melded with daily medical management. The program includes brief daily individual meetings with the staff physician, which often leads to significant medication and additional treatment changes. While preliminary clinical data point to a favorable impact of the DOIT program on glycemic control and diabetes-related emotional distress over a 12-month follow-up period (8), the program has not yet been evaluated in a randomized, controlled fashion. In collaboration with the Tripler Army Medical Center (TAMC) in Hawaii, an expanded version of the DOIT program, which added regular follow-up with a nurse case manager, was developed and evaluated in a randomized two-arm treatment trial, focusing on changes in

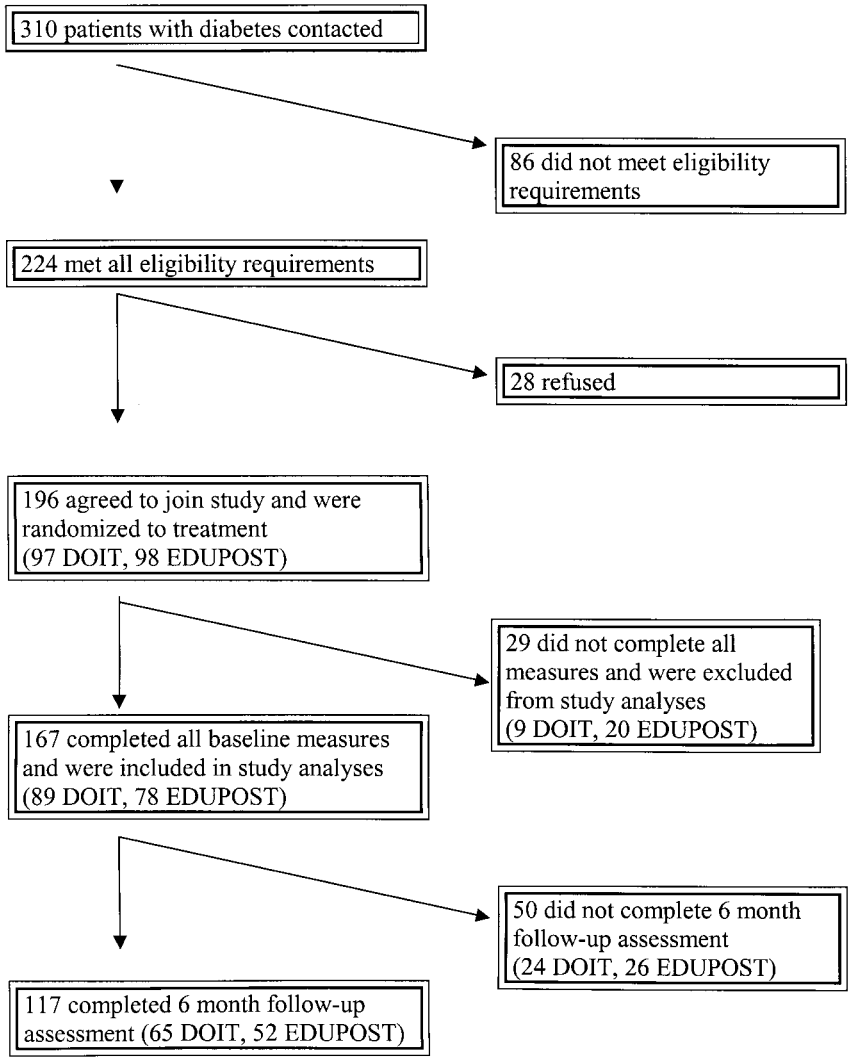

Figure 1—*Patient flow.*

glycemic control and diabetes self-care behavior over a 6-month period.

RESEARCH DESIGN AND METHODS

Subject selection

TAMC is a large general hospital that provides outpatient and inpatient care to ~61,000 active duty members of all military services, 85,000 family members and retirees, 152,000 Pacific Island nation beneficiaries, and ~100,000 veterans. All registered TAMC patients with type 1 or type 2 diabetes, ≥18 years of age, and with a recent (within the previous 3 months) A1c ≥8.5% were considered eligible for the study. The major recruitment method was to identify and target patients in the TAMC database who met eligibility criteria. Identified patients were sent a letter describing the study, which was followed several days later by a phone call from the project's nurse recruiter. Patients were also recruited through mailings to TAMC physicians and through patient-targeted hospital advertisements. Finally, there were additional mailings to physicians at the affiliated Veterans Affairs Medical Center and patient-directed Veterans Affairs advertisements. As seen in Fig. 1, the project recruiter made contact with ~310 patients. Of the 224 who met all eligibility requirements, 196 (88%) agreed to join the study. This project was approved and conducted in strict compliance with TAMC's human research guidelines.

Description of the two study arms

Following completion of all human subject forms, patients were randomly assigned to one of the two treatment arms. The experimental arm was the DOIT program. Group size was limited to 12 patients. The 3.5-day program began with an initial half day of individual evaluation in which patients had one-on-one meetings with the staff physician, nurse case manager, dietitian, and exercise physiologist. This was followed by an introductory group session coordinated by the staff psychologist. On the morning of day 2, the entire staff met to plan the approach for each patient, focusing on achievable lifestyle changes and possible changes in medication regimens. For the patients, days 2–4 consisted of breakfast and lunch buffets (from which they freely choose food under the guidance of the staff dietitian), two supervised exercise sessions, and a series of classes covering the standard American Diabetes Association curriculum, including risk reduction, medication changes, meal planning, exercise, and psychosocial issues. Blood glucose levels were checked (and discussed) before and after meals and exercise sessions, which were designed to encourage patient problem-solving skills and to reinforce the potential value of exercise and good food choices. Each patient also had an individual meeting with the physician each day, during which daily glucose values were reviewed and regimen changes made. In some situations, this led to significant alterations to the treatment regimen. As indicated, there were also individual and small group sessions with staff to review topics such as carbohydrate counting and to introduce new devices (e.g., insulin pens, new lancet choices, and new blood glucose meters). At program end, patients participated in a final behavioral group session where the program was reviewed and individual action goals were determined. Subsequently, the nurse case manager individually reviewed the discharge plan with each patient.

Following the program, the nurse case manager arranged to contact each patient by phone (or, if preferred, in person) on at least a quarterly basis to address problems as they arose, provide support, and adjust the regimen as necessary. There were two cases managers. Both were advance practice nurses with many years of experience in diabetes care, although they were not certified diabetes educators at the time. The case managers met on a weekly basis to discuss patient progress, conduct peer review, and en-

sure consistency of care. They encouraged patients to come in for individual appointments or to call in for telephone follow-up as needed, always focusing on reinforcement of self-management skills as well as medical management (especially medication adjustment). Because case management was designed to be clinically driven for each patient's needs, variability in the number of follow-up contacts was to be expected. More frequent calls were made to patients who were believed by the case mangers to need more regular contact and/or who expressed a direct need for more frequent contact. Because of a lack of response to phone messages, several patients ($n = 3$) had no contact with their case manager over the follow-up period. Overall, during the 6-month period, the median number of contacts was two, although this ranged widely (as expected) from 0 to 17.

Any new clinical intervention, given the influence of patient expectations, may lead to positive behavioral outcomes. Therefore, the second study arm (also presented to patients as an "active" treatment) was titled the EDUPOST program. This consisted of usual diabetes care with the addition of quarterly educational mailings for 12 months. These mailings consisted of Joslin patient brochures: "Overview of diabetes," "Getting to the heart of it," "Meal planning," and "The foot book."

Measures

All clinical and psychometric measures were obtained on a quarterly basis. In this study, only baseline and 6-month data were compared.

Glycemic control

Glycosylated hemoglobin (A1c) was measured by high-performance liquid chromatography; the normal range was 4.0–6.0%.

Diabetes self-care behavior

The Summary of Diabetes Self-Care Activities is a 12-item, self-report scale that assesses frequency of blood glucose monitoring, medication usage, exercise, and dietary behaviors over the previous 7 days (9). We modified several of the scale items and focused our attention on a subset of the items targeting blood glucose monitoring (BGM) ("how often you checked glucose levels," "how often you used glucose results to adjust your diabetes care"), exercise ("how often you participated in at least 20 min of physical exercise"), and dietary behavior ("how often you followed your recommended meal plan," "when making a food choice, how often you considered the carbohydrate or fat content of the product"). For BGM items, response alternatives were "every day," "most days," "some days," and "none of the days." For the exercise item, response alternatives were 0–7 days. For dietary items, response alternatives were "always," "usually," "sometimes," "rarely," and "never." No subscales were created; items were evaluated individually.

Statistical analyses

Baseline differences between DOIT and EDUPOST patients were examined via Student's *t* tests and, where appropriate, χ^2. To determine change in glycemic control and self-care behaviors over time within each treatment condition, we used paired sample Student's *t* tests, comparing values at baseline versus 6 months. Treatment condition differences over the 6-month period were then examined with a series of ANCOVAs in which the dependent variable was the factor of interest at 6 months (A1c or one of the self-care behaviors), the independent variable was treatment condition, and the covariates were age, sex, diabetes type, diabetes duration, and the factor of interest at baseline. In the analysis of treatment impact on A1c, we also examined the differential impact of treatment by sex and treatment by diabetes type. In these cases, the ANCOVAs were repeated with the new variable of interest (sex or diabetes type) being included as an additional main effect variable rather than as a covariate.

Given the variability in follow-up contacts among DOIT patients, we created two separate DOIT groups for the purposes of analysis, "DOIT standard" (two or fewer follow-up contacts) and "DOIT plus" (more than two follow-up contacts). An ANCOVA was then used to determine whether the now three treatment conditions (DOIT-standard, DOIT-plus, and EDUPOST) had a differential impact on A1c at 6 months. The covariates were, once again, age, sex, diabetes type and duration, and A1c at baseline. Planned contrasts examined the differences between the three treatment conditions.

Finally, we collapsed across treatment conditions and explored the associations between glycemic change over time and change in self-care behaviors. A series of multiple regressions were conducted in which the dependent variable was A1c at 6 months and the covariates were age, sex, diabetes type, diabetes duration, A1c at baseline, and computed change in the particular self-care behavior.

RESULTS

Baseline characteristics

Of the 196 patients randomized to the two treatment arms, 29 did not complete the majority of the baseline questionnaire packet (Fig. 1). These 29 did not differ from the remaining 167 in baseline A1c, but they were more likely to have been randomized to EDUPOST ($n = 20$) than DOIT ($n = 9$) ($P < 0.05$). Nevertheless, given the importance of the baseline data, all subsequent analyses were limited to those 167 patients with complete baseline data (78 in EDUPOST, 89 in DOIT).

As seen in Table 1, average age was 50.9 years, education level was relatively high, and patients were evenly divided between the sexes. The subject sample was ethnically diverse. As expected, obesity was common (mean BMI = 30 kg/m^2) and glycemic control was poor (mean A1c = 10.4%). Type 2 diabetes predominated (86.0%), and 36.1% of type 2 patients were taking insulin. Mean duration of diabetes was 11 years. There were no significant differences between DOIT and EDUPOST patients on any of the baseline measures.

Attrition at 6 months

At the 6-month follow-up, A1c values were available for 117 of the 167 patients (52 in EDUPOST, 65 in DOIT) (Fig. 1). Examination of baseline data revealed only two significant differences between patients with and without follow-up A1c values. Those 50 patients without follow-up A1c values were significantly younger than those with follow-up values (mean age was 54 vs. 45 years) ($P < 0.001$). They were also more likely to be active duty military or Veterans Affairs patients (54 and 50%, respectively, had no follow-up A1c available) than military family members or retirees (22 and 23%, respectively) ($P < 0.005$). This suggests that patients may have been lost to follow-up due to reasons mostly unrelated to the two intervention programs (e.g., military assignment out of the area, a restruc-

Table 1—*Baseline characteristics*

Parameters	DOIT	EDUPOST	Total	*P**
n	89	78	167	
Sex (% male)	56.2	51.3	53.9	0.526
Ethnic background (%)				0.389
Caucasian	30.3	38.5	34.1	
African American	20.2	14.1	17.4	
Asian/Pacific Islander	36.0	26.9	31.7	
Hispanic	3.4	6.4	4.8	
Age (years)	48.8 ± 15.2	53.4 ± 15.9	50.9 ± 15.6	0.061
Diabetes duration (years)	9.6 ± 7.9	11.5 ± 10.1	10.5 ± 9.0	0.190
Insulin (% taking)	46.1	42.3	44.3	0.626
Type 2 diabetes (%)	82.6	89.9	86.0	0.092
A1c (%)	10.2 ± 1.7	10.6 ± 1.9	10.4 ± 1.8	0.116
BMI (kg/m^2)	30.3 ± 6.0	29.8 ± 7.9	30.0 ± 6.9	0.691
Education level (% high school graduates)	94.4	89.6	92.2	0.254
Marital status (% married)	83.1	71.8	77.8	0.078

Data are mean ± SD unless otherwise indicated. *P values, comparing differences between DOIT and EDUPOST.

turing of the Veterans Affairs personnel system that took place during the study period).

Glycemic control

Over the 6-month period, there was a significant drop in A1c values in both treatment groups (in both cases, $P < 0.001$), but DOIT patients evidenced significantly greater glycemic improvement than EDUPOST patients ($P < 0.02$) (Table 2). In the DOIT group, mean A1c dropped 2.3 vs. 1.7 percentage points in the EDUPOST group. When the differential impacts of treatment by sex and by diabetes type were examined, neither interaction was significant (in both cases, $P > 0.35$), suggesting that any treatment condition impact on A1c did not differ between the sexes or between types of diabetes.

Diabetes self-care

DOIT patients reported significant improvements in BGM, exercise, and attention to carbohydrate and fat contents (ACFC) over the 6-month period ($P \leq 0.05$), whereas EDUPOST patients evidenced no improvement (Table 2). DOIT patients reported significantly greater improvement than EDUPOST patients in two areas of self-care—frequency of blood glucose monitoring and frequency of ACFC of food. The two groups were similar at baseline in regards to BGM at least once a day (58% of DOIT patients, 62% of EDUPOST patients) but had diverged at 6 months (89% of DOIT patients, 57% of EDUPOST patients). Regarding ACFC (in particular, those who said that they "always" consider carbohydrate and fat contents when eating), the two groups were again similar at baseline (28% of DOIT patients, 22% of EDUPOST patients) but quite different at 6 months (39% of DOIT patients, 11% of EDUPOST). For DOIT patients, glycemic improvement over the 6-month period was significantly associated with self-reported change in ACFC ($r = -0.41$; $P < 0.02$) but not BGM ($r = -0.10$; $P > 0.50$). As would be expected, A1c levels dropped as self-reported ACFC became more regular. For EDUPOST patients, there were no significant links between glycemic change and either of the two self-care behaviors.

Role of follow-up contacts

Number of follow-up contacts among DOIT patients was positively associated with improvement in A1c over the 6-month period (unstandardized $\beta = -0.12$; $P < 0.04$). Indeed, we found a significant difference in glycemic improvement among DOIT patients with more than two follow-up contacts (DOIT-plus; $n = 29$), DOIT patients with two or fewer follow-up contacts (DOIT-standard; $n = 36$), and EDUPOST patients ($P < 0.03$). In the DOIT-plus group, mean A1c dropped 2.6 (from 10.2 to 7.6%) vs. 2.0 percentage points in the DOIT-standard group (from 10.2 to 8.1%) and 1.7 percentage points in the EDUPOST group (from 10.4 to 8.7%). DOIT-plus patients evidenced a significantly greater drop in A1c than EDUPOST patients ($P < 0.01$); neither of the other two contrasts was significant. To illustrate this finding, consider that 48.3% of DOIT-plus patients had achieved an A1c ≤7.0% at 6 months, whereas only 27.8% of DOIT-standard patients and 11.5% of EDUPOST patients had reached this goal. This suggests that multiple follow-up contacts contributed to the differential glycemic improvement observed in DOIT patients. It is important to note that higher baseline A1cs predicted more follow-up contacts ($P < 0.04$), suggesting that the number of contacts was driven, at least to some extent, by the early observations of case managers that certain patients had greater need for close follow-up than others. Number of contacts was not linked to self-reported change in self-care behaviors (in all cases, $P > 0.10$).

Could more aggressive medication management in the DOIT program explain the observed group differences?

Table 2—*Clinical and psychosocial outcomes at 6 months post-treatment*

	DOIT		EDUPOST	
	Baseline	6 months	Baseline	6 months
A1c	10.2	7.9	10.4	8.7§
Self-care*				
Following meal plan†	8.3	8.3	13.5	5.6
ACFC†	27.8	38.9	21.6	11.1§
Days of exercise	2.8	3.6	3.3	3.7
BGM‡	58.3	88.9	62.2	56.8‖
Use BGMs to adjust regimen‡	13.9	33.3	32.4	27.0

*Only selected self-care items are listed. †Percent reporting "always." ‡Percent reporting "most days" or "every day." Significant group differences over the experimental period are §$P < 0.05$; ‖$P < 0.005$.

Changes in medication dosages were not available for study, but we were able to examine insulin use. We considered those 63 patients who were not on insulin at baseline (and for whom we had data at 6 months). At 6 months, 10 of the 63 patients were now on insulin (4 in DOIT-plus, 4 in DOIT-standard, and 2 in EDUPOST). After rerunning the three treatment conditions ANCOVA, this time excluding these 10 patients, the differential group impact on A1c approached but no longer reached significance ($P = 0.06$). The contrast between DOIT-plus and EDUPOST patients remained significant ($P < 0.03$), indicating that, even when excluding those who switched to insulin, DOIT-plus patients achieved better glycemic outcomes.

CONCLUSIONS — Over the 6-month postintervention period, patients randomly assigned to the comprehensive DOIT program evidenced significantly better glycemic control and better self-care (in particular, more frequent BGM and ACFC, according to self-report) compared with patients assigned to EDUPOST, which was merely usual care plus a series of quarterly mailings. These data suggest that DOIT may be an effective intervention for patients with diabetes.

Changes in self-care behavior may have contributed to the observed differences in glycemic improvement. In particular, we found that more frequent ACFC over the 6-month period was associated with enhanced glycemic control among DOIT patients, accounting for 17% of the variance in glycemic change. Although the causal relationship cannot be established with certainty, promoting ACFC, which improved more in DOIT than EDUPOST patients, was a central facet of the DOIT program, and the observed link to glycemic improvement seems understandable given the growing body of evidence pointing to the important role of medical nutrition therapy in diabetes management (10).

Differences in glycemic improvement did not appear to be due to more aggressive medication management, at least when considering those patients who began insulin during the follow-up period. However, frequency of follow-up contacts with the nurse case manager was linked to better glycemic outcomes. Indeed, almost one-half (48.3%) of the DOIT patients who had more than two follow-up contacts achieved an A1c ≤7.0% at 6 months versus only one-quarter (27.8%) of DOIT-standard patients who had two or fewer contacts and only 11.5% of EDUPOST patients. This is consistent with the reviews of Norris et al. (7,11), demonstrating that diabetes self-management interventions followed by regular reinforcement seem to be more effective and, in particular, that the length (i.e., number of contact hours) of self-management programs is positively associated with glycemic improvement. Unfortunately, the current data cannot shed further light on how this effect might come about, because we found that number of contacts was not associated with improvement in diabetes self-management.

Follow-up contact aside, we suspect that other facets of DOIT contributed to the observed differences. First, the careful combination of medical management with diabetes self-management training into an integrated, multidisciplinary program may have been critical. Perhaps if it had been possible to precisely track dosage changes in prescribed medications, including oral hypoglycemic agents as well as insulin, and to objectively assess alterations in self-care behaviors during shorter time intervals, we would have been able to discover group differences that explained a significant proportion of the glycemic findings. In addition, the DOIT program incorporated many of the aspects of successful programs as identified by Norris et al. (7), including an emphasis on patient participation and collaboration as well as a focus on group education.

Several study limitations are apparent. First, ~15% of patients were eliminated from all data analyses because their baseline data were incomplete and these patients were disproportionately represented in the EDUPOST condition. An additional 30% of patients were lost at the 6-month follow-up, although these losses were relatively equal between treatment conditions. Whereas the study sample was ethnically diverse and representative of the Hawaiian population, the ethnic breakdown does not reflect the typical American population (e.g., >30% Asian or Pacific Islander background).

In conclusion, the extended DOIT program appears to be an effective approach toward promoting better diabetes care, contributing to a long-term positive impact on glycemia and diabetes-related self-care behaviors. It is, however, a resource-intensive program that demands significant time, commitment, and careful coordination with many health care professionals. The role of the nurse case manager in providing ongoing follow-up contact appears to be important. Further research is needed to understand how glycemic improvement is achieved, to determine whether other important clinical markers (e.g., blood pressure and lipids) may be similarly influenced and to clarify the long-term influence of the initial program from the impact of ongoing follow-up.

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