

Advanced Insulin Management Program Reduces A1C Levels and Regimen-Related Distress Without Weight Gain in Patients With Type 1 Diabetes Mellitus

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ABSTRACT

Background: Despite the availability of effective treatments, many patients with diabetes have suboptimal glycemic control.

Objective: This study was designed to determine whether the Advanced Insulin Management (AIM) program could help patients with type 1 diabetes mellitus (DM) reduce their A1C levels to $\leq 7.5\%$ without weight gain, increased incidence of hypoglycemia, or increased diabetes-related distress.

Methods: The AIM program, developed to intensify glycemic control in patients with type 1 DM, consisted of a screening visit and 3 to 6 interactive group sessions, depending on whether the patient elects multiple daily injections (MDIs) or an insulin pump. Patients who wanted to learn additional diabetes management skills were referred by their endocrinologist, and those with competent carbohydrate-counting skills and record-keeping practices were eligible to enroll. A nurse, dietitian, psychologist, and physician provided group instruction and supported individual goal setting. The program included depression screening, regimen adjustments, and problem-solving activities. Outcome measures, including blood glucose, A1C, weight, and diabetes-related distress, were tracked for 12 months.

Results: The study included 113 adult patients with type 1 DM (59% female; mean age, 39 years). Twenty patients already had insulin pumps, 46 patients initiated pump therapy during the study, and 47 patients elected MDIs. Mean A1C declined by 0.5% (to 7.3%) after 12 months, without weight gain or increased hypoglycemia. A significant decrease in diabetes-related distress was observed.

Conclusion: The AIM program was associated with important improvements in glycemic control in patients with type 1 DM, without weight gain or increased hypoglycemic episodes. (*Insulin*. 2008;3:59–66) © 2008 Excerpta Medica Inc.

Key words: type 1 diabetes mellitus, insulin pump therapy, multiple daily injections, weight gain, hypoglycemia, quality of life, diabetes-related distress, A1C.

INTRODUCTION

The Diabetes Control and Complications Trial demonstrated that glycemic control for type 1 diabetes mellitus (DM) could significantly delay the onset and progression of micro-

vascular and neuropathic complications.¹ The goal of treating a patient with diabetes is to reduce these complications, and appropriate therapeutic regimens such as multiple daily injections (MDIs) of insulin or continuous subcutaneous

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insulin infusion (CSII; insulin pump), along with successful behavioral modifications, can help to achieve this goal.

Despite the availability of effective treatments, a large percentage of patients with diabetes still have suboptimal glycemic control² and individuals are asking their providers for better methods to control their diabetes. The Epidemiology of Diabetes Interventions and Complications Study showed the importance of early, intensive insulin treatment in patients with type 1 DM.³ Intensive treatment using MDIs or CSII is one aspect of attaining enhanced control. Current evidence also indicates that education and guidance from a diabetes care team are useful in improving control.⁴⁻⁸ The International Diabetes Center has developed an innovative, outcomes-driven, Advanced Insulin Management (AIM) program to assist patients in achieving better control.

The purpose of this study was to determine whether the newly developed AIM program could help patients with type 1 DM reduce their A1C levels to $\leq 7.5\%$ without weight gain or an increased incidence of hypoglycemia. We also compared the results based on the method of insulin delivery (MDIs vs CSII). Assessment of diabetes-specific distress levels was a secondary objective.

Intervention Program

The ongoing AIM program has several unique features. First, the program uses simple screening tools to determine whether patients are ready for MDIs and/or CSII therapy. Patients must be able to count carbohydrates; keep extensive food, blood glucose, and activity records; and be willing to share this information in a group setting. Sample screening questions are included in **Table I**.

Second, the program engages the patient with the physician, nurse, dietitian, and psychologist to share expectations and commitments. All sessions are held in a group setting; patients see each other's food, blood glucose, and activity records, and they discuss ways to improve glucose levels that are out of target range.

Table I. Sample screening questions for the Advanced Insulin Management program.

Are you willing to test your blood glucose 4 to 7 times per day?
Are you willing to test some blood glucose levels at 3 AM?
Would you keep written records of your blood glucose levels?
Are you willing to take 3 or 4 injections of insulin a day?
Do you know how to count carbohydrates?
Are you willing to keep food records?
Would you be able to maintain a consistent meal plan and activity level for a period of several weeks?

Third, the program uses adult learning theory and Stages of Change assessments to deliver education around patient readiness. The Stages of Change model is a concept developed by Prochaska et al,^{9,10} who studied how people effectively change and maintain their behavior.

Fourth, the program develops skills for daily living by placing the patient in real-life, problem-solving scenarios.

Fifth, the program has unique algorithms for dosing and adjusting insulin for patients.

Outcomes are measured at 3, 6, and 12 months.

The AIM program begins with 3 sessions, each lasting 3 hours. The sessions are held once a week for 3 consecutive weeks. The intent of this program is to incorporate components addressing diabetes management skills, knowledge, attitudes, and beliefs in a manner that allows patients to better understand the barriers to achieving their diabetes goals and how to overcome these barriers. A fundamental goal is to assist patients in translating knowledge to practical application. Toward this end, family members are strongly encouraged to attend the program to enhance and support this process.

A licensed psychologist begins the first and third sessions to facilitate group dynamics by having patients become comfortable with each other and sharing concerns related to their diabetes. The psychologist teaches the psychosocial component of the program, which is based on Prochaska's Stages of Change.⁹ The intent is to have patients identify their current stage of change and determine how they can move along the continuum to achieve their desired goals regarding diabetes management. By providing patients with information to help them identify their stage of change and assisting them in moving through these stages, individuals are supported in making beneficial and sustained behavioral changes that will have a positive impact on how they manage their diabetes in daily life. This component of the program is essential in increasing the patients' willingness to embrace changes to achieve their desired outcomes. The psychologist also administers a diabetes-related distress test, scores it, and gives feedback to the patient, physician, nurse, and dietitian regarding barriers that the patient might be experiencing.

Registered nurses who are certified diabetes educators (CDEs) discuss key components of successful diabetes self-management with the group. These topics include the types of insulin to be used, basal and bolus dosing concepts, and anticipatory and compensatory adjustments. Each topic is reviewed and discussed using case scenarios and the patients' current food, activity, and blood glucose records to assist one another in problem solving. The unique dynamic in this program is learning from each other's experiences, learning how to systematically analyze someone else's records, and then applying those skills to their own diabetes management. Individual target blood glucose levels are established, and the patients agree to document their blood glucose levels (using a meter with downloading capability), insulin doses, food intake, and activity for the duration of the 3-week program.

The registered dietitian (also a CDE) assists patients and family members in understanding the impact of portion sizes and carbohydrate content of foods on postmeal blood glucose levels and the importance of determining their insulin-to-carbohydrate ratio for each meal. Experience has demonstrated that although many patients can recite a meal plan, far fewer can actually apply the plan to daily living. Therefore, workstations for the hands-on practice of measuring portions in various ways, analyzing food labels, and counting grams of carbohydrate in foods are used during this component of the program. Patients are also given homework assignments to practice all concepts that have been introduced. Patients measure foods commonly eaten at home and are provided with a resource book on carbohydrate content of foods. Patients are asked to visit a favorite restaurant and use the tools and skills they have learned during the AIM program. Patients record their food intake in grams of carbohydrate and test their blood glucose before and 2 hours after each meal. Patients are also asked to engage in exercise and to test their blood glucose before and after exercise.

The medical director, an endocrinologist, meets with the group each week and assists participants in adjusting their insulin regimens based on the team's assessment of the patients' records for the prior week. Doses are adjusted by balancing total basal and total bolus insulin to approximately a 50/50 ratio, with variations depending on carbohydrate intake and activity level. Mealtime insulin is prescribed based on the formula of giving 1 unit/15 g of carbohydrate (1 carbohydrate choice) per 15 units of basal insulin (eg, a patient on 23 units of basal insulin would be

using 1.5 units/1 carbohydrate choice). A correction factor is then prescribed using the following formula: 60 divided by units/1 carbohydrate choice will determine the decrease in blood sugar per unit of insulin (eg, $60 \div 1.5 = 40$; therefore, 1 unit of rapid-acting insulin will reduce the blood sugar 40 mg/dL). Dosing is then individualized for the patient's needs and responses, and an exercise prescription is given to either subtract insulin or add carbohydrate, depending on the duration and perceived strenuousness of the exercise (Table II). At the end of the 3 sessions, the patient has a revised basal dose, mealtime insulin-to-carbohydrate ratio, a correction factor, and an exercise prescription for adjustment.

After successful completion of the AIM program, patients may elect to continue and undergo CSII training if they want to start using an insulin pump. The CSII program consists of 3 sessions, each lasting 2 hours. The sessions are held once a week for 3 consecutive weeks. The goals of these sessions are to train the patient on the use of the pump, including the advanced features, and to modify doses as needed. Initial pump doses are typically 80% of MDI doses at the end of the AIM program. The total basal dose is determined by multiplying the MDI total basal dose by 0.8. This number is then divided by 24 to calculate the rate (units per hour). For patients with a known rise in blood glucose before waking, the basal rate is increased for 3 hours before their normal waking hour. The correction factor that was determined earlier can be used to determine the magnitude of the increase. For example, if the blood glucose level rises 30 mg/dL from 3 AM to 6 AM and the correction factor is 1/60, the provider would add 0.5 unit of basal insulin over that

Table II. Insulin and carbohydrate (CHO) adjustments for exercise.

Current Insulin/ CHO Choice	Intensity of Exercise (30-min Intervals)	Insulin (Subtract)	CHO Choices (Add)
1	Mild	1/2	1/2
	Moderate	1	1
	High	2	2
1-1/2	Mild	1/2	1/3
	Moderate	1	2/3
	High	2	1-1/3
2	Mild	0	0
	Moderate	1	1/2
	High	2	1
3	Mild	0	0
	Moderate	1-1/2	1/2
	High	3	1
4	Mild	0	0
	Moderate	2	1/2
	High	4	1

Mild = increased activity; moderate = breaking a sweat; high = breathing hard.

time interval. Otherwise, initial basal rates are stable over 24 hours and adjusted based on premeal blood glucose test results. To determine the bolus insulin-to-carbohydrate ratio for the pump, the number of grams of carbohydrate covered by 1 unit of rapid-acting insulin is multiplied by 1.2 (eg, $15 \times 1.2 = 18$; therefore, 18 g of carbohydrate will be covered by 1 unit of insulin).

Throughout the pump training, patients keep food intake, activity, and blood glucose records. Patients call the CDE to obtain assistance in problem solving and making appropriate insulin adjustments. Cases are reviewed with the medical director as needed. After 3 weeks of pump training, patients follow up with their endocrinologist and schedule their next visit (recommended at 1 month after completion of the program).

PATIENTS AND METHODS

Research Design

This was a longitudinal, observational study designed to measure the effectiveness of the AIM program. The study design included a screening phase, a baseline phase, and 3-, 6-, and 12-month follow-up visits. The Park Nicollet Institute's institutional review board approved the study before patients were enrolled.

Study subjects were chosen from patients who were referred by their endocrinologist if they expressed an interest in learning more diabetes management skills than were taught in basic diabetes education. Study participants met the following criteria: (1) diagnosis of type 1 DM before 30 years of age; (2) current age ≥ 18 years; (3) successful completion of the screening questionnaire developed by the diabetes care team (**Table I**); (4) submission of written informed consent before participating; (5) willingness and ability to comply with the clinical recommendations advised by the diabetes care team; and (6) access to a telephone. Patients were excluded if they were pregnant, unable to communicate in English, or unable or unwilling to follow the clinical recommendations advised by the diabetes care team.

The study population participated in the AIM program as described, and was divided into 3 groups for analysis: patients who were already receiving CSII at the beginning of the study, patients who started CSII therapy during the study, and patients who never used CSII (ie, elected and continued to receive MDIs). Patients who were already receiving CSII were enrolled because we found that many pump users needed the skills being taught and would benefit from the program. They perceived their insulin pump as more than simply an insulin delivery system and needed to understand that they still had to function as the "brains" of the system, requiring skills in dosing insulin for anticipated intake of food, adjusting insulin for exercise, and changing rates to accommodate illness and stress.

Measures

Assays of A1C levels were conducted by means of high-performance liquid chromatography using a Bio-Rad Variant

II Turbo analyzer (Bio-Rad Laboratories, Hercules, California) certified by the National Glycohemoglobin Standardization Program. Blood glucose was measured using meters with downloading capability. Patients were weighed at the clinic during the initial visit and at 3, 6, and 12 months.

Diabetes-specific distress was assessed with the Problem Areas in Diabetes 2 (PAID-2) scale, a revision of the original (PAID) scale,¹¹ which has been demonstrated to be reliable, sensitive to change, and clinically useful.¹²⁻¹⁵ The instrument contains 4 subscales of distress: global diabetes distress, physician-related distress, regimen-related distress, and interpersonal distress. The scale ranges from 1 (not a problem) to 6 (serious problem) for 17 questions covering the 4 subscales. Lower PAID-2 scores indicated less distress.

Statistical Analysis

The primary outcomes were changes in A1C levels and weights from baseline to 12-month follow-up. Changes that occurred during the 12-month period were tested using paired *t* tests or Wilcoxon signed rank tests. We also examined the effect of the intervention on PAID-2 scores and the percentage of blood glucose readings < 60 mg/dL. Baseline measures were compared by intervention status (ie, CSII at start, CSII started during the study, or MDIs only) using analysis of variance for continuous variables and χ^2 tests for categorical variables. Multiple linear regression was used to test the effects of age, sex, baseline A1C, weight, PAID-2 distress scores, and CSII status on A1C levels. To evaluate missing data, we compared baseline measures by whether or not 12-month follow-up was obtained using *t* tests or Wilcoxon rank sum tests for continuous variables and χ^2 or the Fisher exact test for categorical variables.

Based on a 2-sided significance level of 0.05 and 80% power, we estimated a sample size of 32 patients per group to detect a 1% difference in A1C level. For all analyses, a 2-sided significance level of 5% was used for statistical inferences. All statistical analyses were performed with SPSS for Windows[®] (Version 14.0) software (SPSS Inc., Chicago, Illinois).

RESULTS

Patient Characteristics

Patient enrollment occurred over a 2½-year period. Most screened patients were enrolled in the study immediately. Those deemed unready for the AIM program were sent for more education and rescreened later if they were still interested in participating. The study population included 113 patients with type 1 DM, 59% female, with a mean (SD) age of 39 (11) years (range, 18–64 years). All patients were white. The education level was high, with 54% having completed college and another 19.5% having attended some college. Twenty patients were already on CSII therapy at the start of the study, 46 patients initiated CSII therapy during the study, and 47 patients never received CSII (ie, they elected and continued to receive MDIs throughout the study). A computer problem led to the loss of some self-monitored blood glucose data. **Table III** shows the baseline characteristics for the 3 groups.

Table III. Mean (SD) baseline characteristics, by CSII (pump) status.

Variable	Pump at Start of Study	No.	Pump Received During Study	No.	MDIs Only	No.	Total	No.	P
Age, y	38.0 (10.1)	20	41.5 (12.1)	46	36.6 (10.7)	47	38.8 (11.3)	113	0.106
Female, %	65.0	20	58.7	46	57.4	47	59.3	113	0.842
Education, % college	65.0	20	52.2	46	51.1	47	54.0	113	0.507
A1C, %	8.42 (1.4)	20	7.49 (1.1)	46	7.94 (1.3)	46	7.84 (1.3)	112	0.016
Weight, lb	172.8 (24.5)	19	178.4 (37.8)	46	172.1 (31.6)	45	174.9 (33.1)	110	0.638
PAID-2, physician	10.6 (3.5)	20	9.2 (2.8)	46	9.6 (4.8)	47	9.6 (3.8)	113	0.398
PAID-2, regimen	21.1 (8.0)	20	14.4 (5.7)	46	17.1 (7.2)	47	16.7 (7.1)	113	0.001
PAID-2, interpersonal	13.6 (5.9)	20	10.7 (3.6)	46	11.7 (5.9)	47	11.7 (5.2)	113	0.111
Hypoglycemia, %	11.6 (8.0)	9	9.0 (7.0)	24	6.4 (6.7)	30	8.1 (7.1)	63	0.114

CSII = continuous subcutaneous insulin infusion; MDIs = multiple daily injections; PAID-2 = Problem Areas in Diabetes 2 scale.

The most noteworthy observation from **Table III** is that patients who were already on CSII at the beginning of the study had significantly higher A1C levels than did patients who began CSII therapy during the study or patients who received MDIs only. Moreover, patients who were on CSII at the beginning also had higher (worse) PAID-2 regimen-related distress scores, suggesting that these patients were experiencing more difficulty in managing their diabetes.

Patients who were already on CSII therapy at the beginning of the study had significantly higher A1C levels than did patients who began CSII therapy during the study or patients who received MDIs only.

Approximately 30% of the patients in the study did not have follow-up A1C data at 12 months. Although no statistically significant baseline differences were observed between patients who had 12-month follow-up data and those who did not, patients without follow-up data tended to have higher baseline A1C values (8.15 vs 7.73; $P = 0.107$). We conducted a separate analysis of the 107 patients who had a baseline value and any follow-up value (between 3 and 12 months); although the mean increased slightly (0.075), the differences were unchanged.

Follow-Up Results

After 12 months, the average A1C value decreased by 0.5% for all patients with follow-up data (**Table IV**). Weight did not change significantly during the 12-month study. A significant improvement was observed in the PAID-2 scores for interpersonal distress, and the improvement in PAID-2 scores for regimen-related distress approached statistical significance.

Weight did not change significantly during the 12-month study.

Multivariate analysis of change in A1C by age, sex, weight, PAID-2 distress scores, and CSII status revealed no significant associations. However, change in A1C was related to baseline A1C ($P < 0.001$); patients with higher baseline A1C levels had greater reductions. Analysis of the changes in A1C and weight by CSII status revealed that each of the 3 groups had decreased mean A1C at 12 months (**Figure**).

Change in A1C was related to baseline A1C ($P < 0.001$); patients with higher baseline A1C levels had greater reductions.

No significant changes in weight occurred between baseline and 12-month follow-up. Hypoglycemia data were available for a subset of patients (**Table IV**), and no significant changes were observed between baseline and 12-month follow-up. After 12 months, PAID-2 regimen-related distress scores improved significantly for those on CSII at the beginning of the study (19.6 to 15.9; $P = 0.028$). For the patients who received MDIs only, the PAID-2 scores for physician-related distress and interpersonal distress improved, but not significantly ($P = 0.11$ and $P = 0.09$, respectively).

DISCUSSION

Results of this study indicate that by following intensive instruction and training in insulin management, patients who begin with moderately well-controlled type 1 DM can

Table IV. Mean (SD) baseline and 12-month follow-up paired comparisons for entire group.

Variable	No. of Patients	Baseline	12-Month Follow-Up	P
A1C, %	81	7.73 (1.1)	7.28 (1.0)	<0.001
Weight, lb	88	174.5 (33.5)	174.2 (34.4)	0.773
PAID-2, physician	60	9.7 (3.4)	9.2 (2.9)	0.287
PAID-2, regimen	60	16.3 (6.9)	15.0 (6.0)	0.059
PAID-2, interpersonal	60	11.8 (4.5)	10.5 (4.8)	0.014
Hypoglycemia, %	26	11.8 (7.9)	10.8 (7.9)	0.473

PAID-2 = Problem Areas in Diabetes 2 scale.

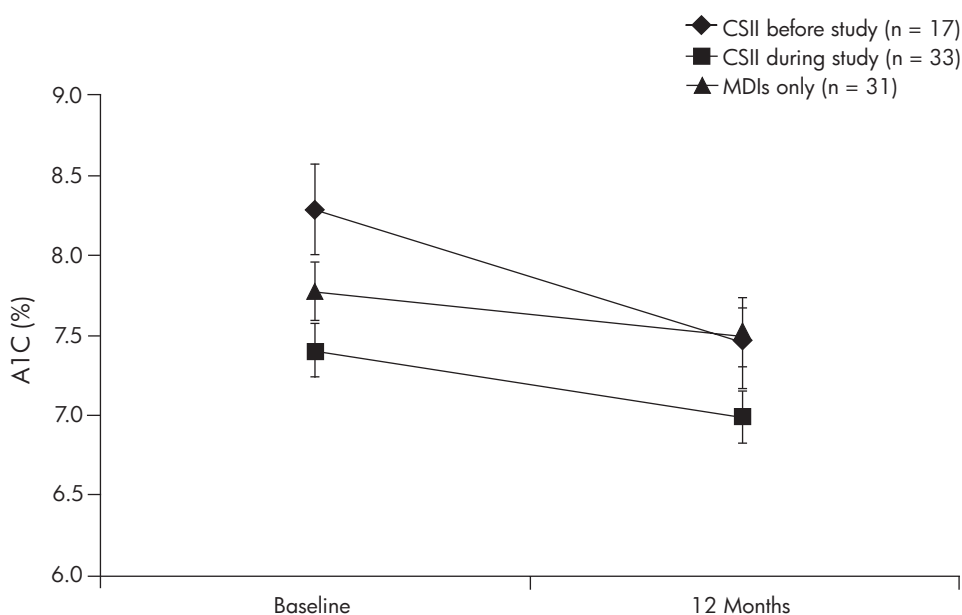


Figure. Changes in mean A1C levels by continuous subcutaneous insulin infusion (CSII) status (n = 81). MDIs = multiple daily injections.

achieve important reductions in their A1C level. The overall mean A1C level 12 months after intervention was 7.3%, and each of the 3 treatment groups had a mean A1C level <7.5%. The mean reduction in A1C level for each treatment group ranged from 0.3% for the group receiving MDIs only throughout the study to 0.8% for the group already on CSII at the beginning of the study. Furthermore, the improved glycemic control was achieved without weight gain, a problem that has been reported by others.^{3,16} In addition, no increase in hypoglycemia occurred, although this result was less robust due to missing data. At 12-month follow-up, 10.8% of blood glucose readings were <60 mg/dL. Bode et al¹⁷ reported normative values of 10% <70 mg/dL, but the measurements were not entirely comparable.

The improved PAID-2 scores for regimen-related distress in patients receiving CSII at the start of the study suggest that

education and training helped these patients understand how to better utilize CSII therapy. Others have shown that CSII can reduce hypoglycemia and improve coping skills in adolescents.¹⁸ Our finding that these patients had higher baseline A1C values was not surprising. We have generally found that many patients on CSII do well for a while, and then their glycemic control deteriorates. Many of these patients do not receive adequate instruction in the beginning and do not fully understand CSII therapy, particularly insulin dosing and adjustment. Patients who started CSII during this study had the smallest changes in PAID-2 distress scores.

The staff involved in this program anecdotally observed the powerful effect of group dynamics during the classroom sessions. We speculate that education delivered in this manner was one of the contributing factors that led to the improved outcomes. More research is needed in this area.

Although these results are encouraging, we note some key limitations of this study. The patients who did not return for 12-month follow-up (28% of the sample) had an average baseline A1C of 8.15%. Assuming that their control did not improve, a significant minority of all enrollees may not have benefited from the program. The findings of our study may not be generalizable because of the unique attributes of our study population; all members of the study group were white and highly educated. Although inconsistent findings have been reported regarding the association between literacy and glycemic control,^{19,20} Goldman and Smith²¹ found that those with more schooling were more adept at diabetes self-management. This will be an increasing issue as diabetes treatments become more complex.

We believe our study raises an important policy question, because 65% of the study patients with follow-up data had A1C values $\geq 7.0\%$ after 12 months, a level at which the American Diabetes Association recommends additional action.²² However, the number of adverse outcomes prevented by improving A1C decreased as baseline A1C was reduced (ie, more absolute risk reduction was achieved by decreasing A1C from 9.0% to 8.0% than from 8.0% to 7.0%).²³ A1C levels $< 7.0\%$ may be unrealistic or unattainable for some patients, particularly those with type 1 DM.

More broadly, it is accepted that patients with diabetes need education to self-manage their disease. Although the most effective method for delivering education and teaching self-management skills is unclear, many patients still receive cursory education. In our program, patients received 9 hours of advanced-level diabetes education over 3 weeks, which was presented in a group setting and involved both homework assignments and real-time feedback on their results. Sperl-Hillen and O'Connor²⁴ found that resources spent on nurse and dietitian educators were associated with improved

levels of A1C and low-density lipoprotein cholesterol. Thus, the policy question may be how to find the resources needed for improving diabetes education.

Finally, a number of studies have suggested that intensive maintenance is required to prevent glycemic relapse in patients with type 1 DM.²⁵⁻²⁷ Graber et al²⁸ also recently described a relapse phenomenon in patients with type 2 DM, in which patients who were receiving insulin therapy were at particular risk of glycemic relapse. Thus, it is likely that "booster" sessions of advanced instruction and training in insulin management are needed to maintain gains in glycemic control. Again, more resources would be needed to provide periodic additional education to patients with diabetes.

CONCLUSIONS

The AIM program was associated with important incremental gains in glycemic control in these patients with type 1 DM, without weight gain or an increase in hypoglycemic episodes. More intensive approaches like the AIM program are needed to achieve better glycemic control, even in moderately well-controlled populations.

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