Failure to Maintain the Benefits of Home-Based Intervention in Adolescents With Poorly Controlled Type 1 Diabetes

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OBJECTIVE — To determine whether a 6-month home-based intervention program in adolescents with poorly controlled diabetes improves metabolic control and whether benefits are maintained after the intervention.

RESEARCH DESIGN AND METHODS — Adolescents with a mean HbA_{1c} of >9.0% over the preceding 12 months received either routine care in a diabetes clinic and an ambulatory intervention for 6 months (n = 37) or routine care only (n = 32). A diabetes educator provided monthly home visits and weekly phone contact to educate and support the adolescents in setting goals for insulin adjustment, blood glucose monitoring, and target blood glucose range. There was no systematic change in the frequency of insulin injections. After the intervention, there was a 12-month follow-up when the intervention and control groups both received only routine care. Outcome measures were HbA_{1c} and Diabetes Knowledge Assessment (DKN).

RESULTS — During the intervention, mean HbA_{1c} fell (baseline: 11.1 ± 1.3%, 6 months: 9.7 ± 1.6%; P = 0.0001) and mean knowledge scores increased (P = 0.0001) in the intervention group but not in control subjects. However, this improvement in HbA_{1c} and increase in knowledge was not maintained in the intervention group at 12- and 18-month follow-up assessments. Parents' knowledge scores also improved significantly from baseline levels in the intervention group at 6 and 12 months (P = 0.001, P = 0.005, respectively).

CONCLUSIONS — An ambulatory program improves metabolic control and knowledge in adolescents with poorly controlled type 1 diabetes; however, it is effective only while the intervention is maintained.

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The major contribution of metabolic control during adolescence to the risk of progression of microvascular complications in type 1 diabetes is now clearly understood (1–4). Metabolic control frequently deteriorates during puberty because of physiological (5) and psychological changes (6). The 195 adolescents in the Diabetes Control and Complications Trial (DCCT) randomized to intensive insulin therapy required more education and support than adults to achieve a comparable improvement in HbA_{1c} (1). Their HbA_{1c} levels were higher than those in adults in both intensive and conventional therapy groups. However, despite having higher levels of HbA_{1c}, they experienced more hypoglycemia than adults (1). Increased education and support probably played a significant role in the improved metabolic control that was achieved, but their effect cannot be separated from the effect of concurrent intensive management.

Implementing intensive insulin therapy in some adolescents with poor metabolic control can be difficult because of problems with adherence. There is evidence that adolescents omit 25% of their insulin injections and frequently fail to monitor blood glucose levels, and that both parents and doctors underestimate this behavior (7). Insulin omission is the most common cause of diabetic ketoacidosis in adolescence (8,9), and, although programs have successfully prevented recurrent ketoacidosis (9), attempts to improve metabolic control in many high-risk patients have not been successful (10). Adolescents' decisions about whether to adhere to treatment are influenced by a range of factors, including improved knowledge, the nature of the social support they receive, the quality of their relationships with health professionals, and the nature of the treatment regimen (11).

In addition to problems with adherence, adolescents with poor metabolic control often have problems accessing health services, further impeding the implementation of intensive therapy.

We evaluated a 6-month home-based intervention provided by a diabetes nurse educator. The program aimed to improve metabolic control by improving knowledge and individual goal setting in adolescents with poorly controlled type 1 diabetes without a systematic change to intensive therapy. We also aimed to determine the longer-term outcome 12 months after the intervention.

RESEARCH DESIGN AND METHODS

— Subjects were 73 adolescents with poorly controlled type 1 diabetes as defined below. The Women's and Children's Hospital diabetes clinic cares for >75% of the patients aged <18 years in South Australia. Participation rate of eligible patients was 94%. Four patients failed to have complete follow-up or had missing HbA_{1c} data and were excluded from analysis, leaving 69 patients in the study.

Inclusion criteria were: 12–17 years old, duration of type 1 diabetes of >1 year,

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Abbreviations: ANOVA, analysis of variance; DCCT, Diabetes Control and Complications Trial; DKN, Diabetes Knowledge Assessment.

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

Table 1—*Baseline characteristics of intervention and control subjects*

	Intervention	Control	*P*
n (female)	37 (19)	32 (22)	—
Age (years)	14.2 ± 1.7	14.3 ± 1.9	0.86*
Duration of type 1 diabetes (years)	7.08 ± 3.6	5.83 ± 3.0	0.12*
Insulin dose ($U \cdot kg^{-1} \cdot day^{-1}$)	1.22 ± 0.32	1.20 ± 0.29	0.91†
Two injections/day	30	26	—
Three injections/day	5	4	—
Four injections/day	2	2	—
Family structure (%)			
Two parents	83	75	0.21*
Single parent	17	25	—
Father's occupation status (%)‡			
High	22	9	0.33*
Medium	41	41	—
Low	14	14	—
Pensioner/unemployed	5	9	—
Missing	19	28	—

Data are *n*, means ± SD, or %. *Independent samples *t* test comparing intervention and control groups. †χ^2 test comparing intervention and control groups. ‡From Power (24).

mean HbA_{1c} over the last year of >9.0% (this HbA_{1c} level was >1 SD above the mean of 8.3% for the 212 adolescents in the clinic population), and sufficient comprehension of the English language to answer the questionnaires used in the study.

For the purpose of the study, Adelaide was divided into two geographic regions of equivalent socioeconomic status as determined by the 1993 Australian Census data, Australian Bureau of Statistics (12). Thirty-seven adolescents living in one geographic region (southeast) received the intervention; 32 adolescents living in the other geographic region (northwest) received routine care. Subsequent analysis after recruitment detected no difference in socioeconomic status between control and intervention groups as indexed by parents' educational attainment and occupation (Table 1). This approach of identifying the intervention and control groups by means of where the adolescents lived was adopted to allow travel by the nurse educator to be kept to manageable limits. However, there may have been other differences between the intervention and control groups that we did not detect.

The 37 patients in the intervention group received monthly home visits by a diabetes nurse educator, who also provided weekly phone contact. All subjects completed all monthly visits during the intervention. Six subjects missed one phone call contact because of school holidays. Each phone contact was for 5–10 min; each home visit was for 45–60 min. A manual was prepared at the beginning of the study and the monthly sessions covered in sequence.

During the initial home visit the nurse educator discussed the adolescent's feelings about his/her diabetes and general health beliefs and also evaluated the adolescent's knowledge of diabetes. Each subject was given a written synopsis of the DCCT outcomes, which were discussed in initial home visits (1). The adolescents set their own goals for frequency of blood glucose monitoring and insulin adjustment according to target blood glucose levels, aiming to reach their individually chosen target blood glucose and HbA_{1c} levels at 3 and 6 months, respectively. To help them achieve these goals, the adolescents received further structured education on long-term significance of metabolic control, nutrition, exercise, sick-day management, hyperglycemia, hypoglycemia, and insulin adjustment. To aid this education, five case scenarios were presented for discussion—a school sporting event, a weekend holiday with friends, an evening social function, a school camp, and advice to a friend with diabetes who has poor control. Events that made it more or less difficult to adhere to their goals were identified and discussed, including negotiation skills and conflict resolution. Anger, sadness, and motivation were discussed (no subject was receiving concurrent psychological support from a psychiatrist or psychologist during the study). A strong interest in other aspects of the adolescent's life was maintained by the nurse educator. Each phone consultation was initially directed toward their other interests. Parents were not formally involved in the home visits and did not receive direct education; however, they were usually present in the home at the time of the visit and were invited to receive a summary of what had been discussed at the end of each monthly session.

Adolescents in the control and intervention groups continued to receive routine care, which consisted of hospital visits at 3-month intervals for review of their diabetes by a pediatric endocrinologist, dietitian, and diabetes educator, as well as the availability of 24-h phone access for acute problems. Health professionals who cared for the patients in the study were not aware of the group to which the adolescent had been assigned. Insulin dose and frequency were adjusted according to standard clinical management independent of the group to which the adolescent was assigned. Patients received twice-daily or three-times-daily insulin; there was no systematic change in the frequency of insulin injections associated with this study.

After the 6-month intervention, there was a 12-month follow-up period when adolescents in the intervention and control groups both received routine care. HbA_{1c} levels were measured at baseline and at 6 (i.e., immediately after intervention), 12, and 18 months by high-performance liquid chromatography (normal range 4–6%). Interassay coefficient of variation is 0.2% (13).

Adolescents' knowledge of diabetes was assessed at 0, 6, 12, and 18 months by means of the Diabetes Knowledge Assessment (DKN) Scale (14). The DKN Scale is a 15-item questionnaire that is designed to provide a reliable assessment of the knowledge of patients about the management of type 1 diabetes. Respondents are required to select one or more correct answers from several choices following each of the 15 items that compose the scale. A total score is generated on the basis of the number of correct answers given to the 15 items. The content and format of the questionnaire were evaluated in a study of 300 patients, and the internal reliability is reported to be 0.82 (Cronbach's α). Scores on the scale also had a high correlation ($r = 90$) with other scales designed to measure knowledge of diabetes management (14).

Baseline characteristics of the intervention and control groups are shown in Table 1. During the course of the 18-month study

Table 2—*HbA_{1c} levels of adolescents and insulin regimens in the intervention and control groups*

	Assessment			
	Baseline	6 Months	12 Months	18 Months
Intervention group (n = 37)				
HbA_{1c}	11.1 ± 1.3*	9.7 ± 1.6	10.5 ± 1.8	10.0 ± 1.5
Insulin dose (U · g^{-1} · day^{-1})	1.22 ± 0.32	1.29 ± 0.28	1.30 ± 0.37	1.20 ± 0.41
Insulin × 2/day	30	30	30	30
Insulin × 3/day	5	5	5	5
Insulin × 4/day	2	2	2	2
Control group (n = 32)				
HbA_{1c}	10.5 ± 1.6	10.3 ± 2.2	10.7 ± 2.0	10.5 ± 1.8
Insulin dose (U · g^{-1} · day^{-1})	1.20 ± 0.39	1.30 ± 1.27	1.28 ± 0.33	1.21 ± 0.43
Insulin × 2/day	26	26	27	27
Insulin × 3/day	4	4	3	3
Insulin × 4/day	2	2	2	2

Data are means ± SD or n.

period, the frequency of insulin injections was decreased in one patient in the control group (Table 2). Total insulin dose (U · kg^{-1} · day^{-1}) did not change significantly in either group throughout the study.

Statistical analysis

The analysis of results compared HbA_{1c} levels and knowledge levels in the intervention and control groups at baseline and at the 6-, 12-, and 18-month follow-ups. The statistical significance of differences between the mean scores was assessed using a series of 2 (index versus control group) × 4 (baseline, 6-, 12-, and 18-month) repeated measures analyses of variance (ANOVA) with a Huynh-Feldt correction procedure. The analyses determined whether differences between the two groups varied significantly across the four assessments (i.e., whether there was a significant group × time interaction for scores on the three variables being studied). Statistical significance was defined as $P < 0.05$.

RESULTS — The mean HbA_{1c} levels in the two groups are shown in Table 2. There was no significant difference between HbA_{1c} at baseline in the intervention and control groups. Repeated measures ANOVA revealed a significant group × time interaction for the HbA_{1c} levels in the two groups [$F(3,201) = 4.4$, $P = 0.006$]. Post hoc tests showed that there was a significant decline in the mean HbA_{1c} level in the intervention group from the baseline assessment to the 6-month assessment [$F(1,36) = 23.2$, $P = 0.0001$]. The difference between HbA_{1c} levels at baseline and the 12-month assessment in the intervention group was not significant while the difference between the baseline and the 18-month assessment approached significance [$F(1,36) = 3.9$, $P = .06$]. In the control group, there was no significant difference between the baseline HbA_{1c} level and HbA_{1c} levels at each of the later assessments. None of the differences between the index and control group HbA_{1c} levels at the four assessments were statistically significant. It is likely that this reflects the weaker statistical power of the between-group comparisons used in this latter analysis.

The mean knowledge scores reported by adolescents are shown in Table 3. There was no significant difference between baseline knowledge scores between the two groups. There was a significant group × time interaction for the knowledge scores in the two groups [$F(3,147) = 3.29$, $P = 0.03$]. Post hoc tests showed that there was a significant increase in knowledge scores of adolescents in the intervention group from the baseline assessment to each of the subsequent follow-up assessments [6 months: $F(1,29) = 34.0$, $P = 0.0001$; 12 months: $F(1,29) = 13.8$, $P = 0.0009$; 18 months: $F(1,29) = 23.4$, $P = 0.0001$]. In the control group, no significant change in score from the baseline assessment to the 6-month follow-up assessment was detected, although the differences between the baseline score and the scores at 12- and 18-month assessments were significant [12 months: $F(1,20) = 8.9$, $P = 0.007$; 18 months: $F(1,20) = 8.9$, $P = 0.007$]. The only significant difference between the scores in the two groups occurred at the 6-month follow-up assessment where the knowledge score of the adolescents in the intervention group was significantly higher than that of the adolescents in the control group [$F(1,49) = 12.0$, $P = 0.001$].

The mean knowledge scores reported by parents are shown in Table 3. The pattern of differences between parent scores was similar to that reported by the adolescents. The group × time interaction was significant [$F(3,144) = 3.3$, $P = 0.04$]. Post hoc tests showed that in the intervention group, differences between the baseline score and scores at each of the subsequent assessments were significant [6 months: $F(1,29) = 10.1$, $P = 0.003$; 12 months: $F(1,29) = 6.6$, $P = 0.02$; 18 months: $F(1,29) = 4.5$, $P = 0.04$]. In the control group, none of the differences between the baseline score and scores at the subsequent assessments were significant. Differences between scores across the two groups were not significant at the baseline assessment, but at the 6- and 12-month assessments parent knowledge scores in the index group were significantly higher than those in the control group [6 months: $F(1,48) = 11.5$, $P = 0.001$; 12 months: $F(1,48) = 13.2$, $P = 0.005$]. At the 18-month assessment, however, no significant differences between scores in the two groups were found.

CONCLUSIONS — The home-based intervention achieved a significant improvement in HbA_{1c} levels in adolescents with poorly controlled diabetes and a small par-

Table 3—*Knowledge scores of adolescents and parents in the intervention and control groups*

	Assessment			
Study group (n)	Baseline	6 Months	12 Months	18 Months
Adolescents				
Intervention (30)	11.6 ± 1.5	13.4 ± 1.3	12.8 ± 1.6	13.2 ± 1.4
Control (21)	11.1 ± 2.4	11.8 ± 2.1	12.3 ± 1.8	13.0 ± 1.3
Parents				
Intervention (30)	12.6 ± 2.5	13.7 ± 1.0	13.7 ± 1.0	13.5 ± 1.5
Control (20)	12.7 ± 1.6	12.4 ± 1.6	12.7 ± 1.5	13.1 ± 1.4

Data are means ± SD.

allel improvement in diabetes knowledge in both adolescents and parents. However, these benefits were not maintained over the 12 months after the intervention. Although the change in HbA_{1c} in the intervention group from baseline to 18 months (12 months after the intervention) appears clinically significant, it did not reach statistical significance. The initial improvement in metabolic control occurred with increased support, increased education, and goal setting without change in the diabetes treatment regimen. Interestingly, parents' knowledge improved during the intervention even though they were not directly included in the program.

Previous studies in adolescents with diabetes have not assessed the short- or long-term effects of a home intervention program. However, support from health professionals, education, and family guidance have all been identified as important in improving metabolic control during adolescence (1,15–17). Adolescents with diabetes also benefit from negotiation skills in terms of treatment responsibilities and treatment goals (18,19). These factors were incorporated into this intervention program.

The DCCT showed that any improvement in metabolic control, however poor that control may be, reduces the risk of complications (20). The improvement in mean HbA_{1c} from 11.1 to 9.7% achieved by the intervention group, if maintained, would translate into a significant risk reduction in the development of microvascular complications (20). The benefits of intensive insulin therapy and intensive management, used to improve metabolic control in the DCCT, have been proven in adolescents (1). However, adolescents with poorly controlled diabetes and poor family support often have difficulties adhering to their diabetes regimen and accessing health professional support so that intensive management may not be implemented successfully (10,21). This study was designed to test another strategy to improve control in this challenging group of patients. A home-based intervention was adopted to overcome the problems with regular clinic attendance that these patients may encounter.

There have been few ambulatory studies in children and adolescents with chronic disease. A 2-year study (1-year intervention; 1-year follow-up) involving 89 children with chronic asthma also failed to sustain benefits of the intervention (22). Home visits by a specialty nurse, in addition to routine treatment and follow-up, improved small airway function, reduced hospital admissions, and improved responsibility of the asthmatic child compared with control subjects. Within 1 year of follow-up, these treatment effects were lost (22).

It appears that an ambulatory program can significantly improve outcome measures in children and adolescents with a chronic disease. However, improvements are maintained only while they continue to receive the program. Daily activities during adolescence are typically less structured than during childhood, making long-term adherence and goal setting more difficult. Adolescents are maturing cognitively and emotionally and are likely to require an ongoing program to help those with problems managing their diabetes. Ambulatory programs are labor-intensive and time-consuming because of travel requirements and are, therefore, costly. Their impact in comparison with potentially less costly and less time-consuming developments, such as support using telemedicine facilities, has not been evaluated. However, the eventual individual gains and savings to the community would be substantial if improved metabolic control could be maintained and the risk of long-term microvascular complications reduced. There is a need to design and evaluate longer-term interventions for this challenging group of adolescents. Our findings also emphasize the need for long-term follow-up to adequately evaluate intervention programs in adolescents that are successful in the short term (23).

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