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Diabetes Personal Trainer Outcomes:

Short-term and 1-year outcomes of a diabetes personal trainer intervention among youth with type 1 diabetes

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Abstract

OBJECTIVE—To assess the social-cognitive, behavioral, and physiological outcomes of a self-management intervention for youth with type 1 diabetes.

RESEARCH DESIGN AND METHODS—A total of 81 youth with type 1 diabetes aged 11–16 years were randomized to usual care versus a “diabetes personal trainer” intervention, consisting of six self-monitoring, goal-setting, and problem-solving sessions with trained non-professionals. Assessments were completed at baseline and multiple follow-up intervals. A1C data were obtained from medical records. ANCOVA adjusting for age and baseline values were conducted for each outcome.

RESULTS—At both short-term and 1-year follow-up, there was a trend for an overall intervention effect on A1C (short-term $F = 3.71$, $P = 0.06$; 1-year $F = 3.79$, $P = 0.06$) and a significant intervention-by-age interaction, indicating a great effect among older than younger youth (short-term $F = 4.78$, $P = 0.03$; 1-year $F = 4.53$, $P = 0.04$). Subgroup analyses demonstrated no treatment group difference among younger youth but a significant difference among the older youth. No treatment group differences in parent or youth report of adherence were observed.

CONCLUSIONS—The diabetes personal trainer intervention demonstrated significant effects in A1C among middle adolescents.

It is well-established that a deterioration in glycemic control accompanies adolescence (1), in part due to hormonal changes associated with puberty (2) but also resulting from worsening adherence (3,4). Consequences include hospitalizations and even mortality from diabetic ketoacidosis (5) and physical damage leading to later complications (6). Because diabetes management during childhood is associated with adult behavior and health outcomes (7,8), intervention to enhance diabetes self-management skills may be critical in decreasing the rate of physical health problems throughout the lifespan.

Optimal diabetes management is a formidable undertaking for youth, who are still maturing cognitively and socially. Typically, self-management skills are not well developed, and

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

evaluation of behavioral options and consequences may be inadequate. Despite concerns regarding readiness for diabetes management responsibility, increased independence from parents often results in youth assuming additional responsibility at the cost of poorer adherence.

The development of effective intervention models during this transitional period is critical and may be facilitated by predominant theoretical perspectives. Social cognitive theory (9) emphasizes the reciprocal relationship of beliefs and social/environmental factors. One's outcome expectations (expected positive and negative outcomes of behaviors) and self-efficacy (perceived ability to perform behaviors) develop from experience, are influenced by cognitive and behavioral skills, and affect subsequent behavior (10,11). These beliefs provide the underpinnings for motivation and self-management processes, as emphasized by the self-regulation model (12), which explains health-related behavior as a function of appraisal of the situation, perceived choice of actions, and evaluation of the outcomes of those actions (13, 14). In diabetes management, the regimen complexity and imperfect correspondence between behavior and disease control can hinder adherence. Self-regulation might be enhanced through instruction in problem-solving skills, role playing and rehearsal, guiding the use of skills in real-life situations, and reinforcing their use and refinement. An assessment of current practice itself provides feedback and a set of possible goals, the achievement of which can be motivating. Facilitated goal attainment, then, should increase both self-regulation skills and beliefs supporting the use of these skills.

Interventions targeting self-regulation skills have been effective in promoting behavior change for various health-related behaviors (e.g., 15,16) and may also improve diabetes self-management, especially among youth who are demonstrating greater difficulty or who have inadequate environmental support (17). Various self-regulation techniques, including self-monitoring, goal-setting, problem-solving, modeling, role-playing, contracting, and reinforcement, have demonstrated efficacy in achieving positive short-term behavioral outcomes in small studies of children with diabetes (18–24). Long-term improvements in glycemic control were observed in two larger trials: a coping skills training intervention in which social problem solving was a core skill (25) and a self-management intervention targeting newly diagnosed children (26).

This literature suggests that a behavioral self-regulation approach would be efficacious in assisting youth to better manage diabetes, as they increasingly must engage in diabetes management activities in the absence of their parents. The effectiveness of this approach may be facilitated by *1*) incorporating principles of motivational interviewing (27,28) to enhance engagement and *2*) using an individualized experiential learning approach. Trained nonprofessionals served as interventionists to allow for a substantial amount of one-on-one time and to determine whether they could effectively deliver this approach. The objective of this study was to assess the cognitive, behavioral, and physiological outcomes of a self-regulation intervention for youth with type 1 diabetes delivered by nonprofessionals and given the important developmental changes that occur from pre- to middle adolescence to assess differing intervention effects by age.

RESEARCH DESIGN AND METHODS

Youth-parent dyads were recruited from two pediatric endocrinology clinics in Baltimore, Maryland, serving a multistate area. Youth aged 11–16 years were eligible if they had been diagnosed with type 1 diabetes for at least 1 year and had no other major chronic illness or psychiatric diagnosis. Of 113 eligible youth, 81 (72%) consented to participate. The sample size was estimated to provide adequate power to detect a 0.5 group difference in A1C.

Participants were recruited during routine clinic visits; informed written consent and assent were obtained. Baseline assessments were scheduled by telephone and conducted in person by trained interviewers not affiliated with the clinic in the participant's home or at another location selected by the parent. Parents and children completed assessments simultaneously but with different interviewers in different areas of the home.

Random assignment was stratified by two categories of age (11–13 vs. 14–16 years) and A1C (<8.0 vs. ≥8.0%), for a total of four strata. Subjects were randomized independently within strata, using a computerized random-number generator and a blocked randomization scheme having a block size of eight.

Follow-up telephone assessments of both parent and youth were conducted postintervention and 6 months postbase-line. In-person assessments were completed 1 year after baseline, using the same procedures as the baseline assessments, with interviewers blind to group assignment. A1C data were obtained from clinic records. The study protocol was approved by the National Institute of Child Health and Human Development Institutional Review Board, as well as the Western Institutional Review Board (for participating clinical sites).

Intervention

The intervention was designed to enhance the youth's motivation and capability for diabetes management. The term "personal trainer" was chosen to emphasize the development of strengths rather than the amelioration of deficits. The role of the personal trainer as a facilitator of the prescribed medical regimen, but not a provider of medical advice, was clearly explained to families. The approach was guided by principles of motivational interviewing, applied behavior analysis, and problem solving. Motivational interviewing was incorporated to facilitate engagement and avoid the personal trainer being perceived as another authority figure, facilitating the personal trainer's use of applied behavioral analysis to guide the youth toward the identification of management goals rather than dictating them. The intervention was delivered in six in-home or public-location (45% of participants, generally due to family living a long distance from clinic) semistructured sessions, supplemented with telephone calls, conducted over approximately 2 months by trained nonprofessionals (bachelor degree and/or graduate students in health-related fields). The initial intervention session was conducted with both youth and parent; subsequent sessions were with the youth only. Every attempt was made to facilitate the youth's use of existing family relationships and skills in a helpful way. The youth experienced skill development associated with identifying areas for improvement, selecting goals, and generating solutions but then was instructed to identify ways a parent could assist and share these with the parent during the session.

The interventionists received ~80 h of training in diabetes management, motivational interviewing, applied behavior analysis, parent-child issues in diabetes management, safety, ethics, and the intervention activities. Training activities included didactic sessions, reading materials, video, role plays, group activities, and individual practice with feedback. Personal trainers participated in weekly group supervisory meetings. Intervention sessions were tape recorded and monitored to ensure intervention fidelity. A sample of intervention sessions was coded along relevant motivational interviewing dimensions (e.g., reflective listening, open-ended questions, empathy, egalitarianism) and specific intervention components; adequate competence and fidelity were observed for all trainers.

The first intervention visit included rapport building, program overview, and review of blood glucose monitoring records. Youth were provided with an accelerometer and food diary (paper form or Palm Pilot software) and instructed to wear the accelerometer at all times and record all food consumption (time, food, and amount) for 2 weekdays and 1 weekend day.

The second visit was designed to continue assessment and begin building motivation for behavior change. The youth and personal trainer reviewed the self-monitoring data, noting frequency, duration, and intensity of physical activity; frequency and timing of blood glucose monitoring; and frequency, timing, and content of meals. A semistructured interview, guided by motivational interviewing principles, was conducted to identify areas of difficulty and develop a list of potential goals. Youth rated their readiness to change on each goal, and additional questions elicited motivation to change and barriers to change. Youth then selected their top three potential goals.

The third visit took the youth through the steps of the behavior-change process. Youth discussed pros and cons of each potential goal and analyzed antecedents and consequences of the potential target behaviors. The youth selected one goal to work on and was led through the process of developing a personal plan, including brainstorming and selecting strategies, addressing potential barriers, defining parent's role in facilitating the plan, determining a method to record progress, and anticipating expected outcomes.

The final three visits focused on follow-up and continued skill development. Youth were assisted in analyzing the results, trouble shooting, problem solving, and revising their plan as needed, facilitating their ability to work toward self-selected goals and assess progress, a process that should be reinforcing and lead to increases in outcome and efficacy expectations. The personal trainers provided suggestions, encouragement, and positive feedback.

Educational control

Families randomized to the educational control condition received the same assessments as the intervention group; timing of the assessments was linked to the timing of intervention family assessments. Control families received an educational booklet entitled *Blood Glucose Monitoring Owner's Manual*, published by Joslin Diabetes Center and based on materials used in an effective psychoeducational intervention (29). Diabetes clinics were blind to the assignment of intervention and control families; both groups received the same standard diabetes care.

Measures

A1C—A1C, the primary outcome, was assessed as per standard care protocol at the clinics. Data were extracted from medical records for the duration of the study, beginning at the recruitment visit. Because A1C values were not obtained from the same lab for all participants, values were standardized by calculating the percent above the upper limit of the normal range for each assay (which ranged from 5.9 to 6.2). Each participant used the same lab across measurements, and all A1C analyses control for baseline values.

Adherence—Adherence was assessed at baseline and each follow-up using a modified version of the Diabetes Self-Management Profile (30). The Diabetes Self-Management Profile was modified to standardize wording, permitting administration by nonmedical interviewers (31). The modified Diabetes Self-Management Profile includes 29 items assessing insulin administration, self-care adjustment, dietary practices, blood glucose monitoring, and exercise. An overall score was derived by averaging the scores across each domain, representing the proportion of adherence to an optimal diabetes regimen (possible scores of 0.00 –1.00). The Cronbach's α at baseline was 0.75 for parents and 0.70 for youth; parent-child agreement was moderate (r = 0.51).

Self-efficacy and outcome expectations—The Self-Efficacy for Diabetes Self-Management scale and the Outcome Expectations of Diabetes Self-Management Positive and Negative scales (32) were administered at baseline and each follow-up. Self-Efficacy for

Diabetes Self-Management scale (10 items, Cronbach's α = 0.93) assesses confidence in one's ability to carry out the diabetes regimen in the face of situational barriers. The Outcome Expectations of Diabetes Self-Management Positive scale (12 items, Cronbach's α = 0.87) and the Outcome Expectations of Diabetes Self-Management Negative scale (12 items, Cronbach's α = 0.90) assess strength of beliefs in positive and negative outcomes of diabetes management activities (α values from the current study). The measures have demonstrated good internal constancy and predictive validity (32).

Quality of life—The Diabetes Quality of Life scale (33) was administered at baseline and 1-year follow-up. The measure consists of three subscales: impact (23 items, Cronbach's α = 0.79), worry (11 items, Cronbach's α = 0.84), and satisfaction (17 items, Cronbach's α = 0.92) (α values from the current study).

Intervention satisfaction—Children and parents in the intervention group completed a questionnaire assessing their satisfaction with the program. They responded to questions regarding perceived usefulness of the program and helpfulness of the personal trainer on a 1–6 scale ("strongly disagree" to "strongly agree") and to open-ended questions regarding program likes, dislikes, and improvements.

Analyses

Content analysis was conducted on the goals selected, categorizing goals to regimen areas. Descriptive analyses were conducted on the intervention satisfaction questions. To assess both short- and longer-term outcomes while including the maximum available A1C data, two mean A1C values were calculated: postintervention through 9 months post-baseline (short term) and 10–18 months postbaseline (1 year). In parallel fashion, the mean of the postintervention and 6-month values were calculated creating a single short-term value for each self-report outcome (adherence, self-efficacy, and outcome expectations). Quality of life was only assessed and analyzed at 1-year follow-up. ANCOVA was conducted on each outcome variable (A1C, adherence, self-efficacy, outcome expectations, and quality of life) at each follow-up period, with the baseline value of the outcome variable and age as covariates. Interaction of each outcome variable with age was tested; significant interactions were retained in the final models. For those variables demonstrating significant interactions by age, a stratified analysis was conducted, with separate models run for youth aged 11–13 years and those aged 14–16 years.

RESULTS

Demographic characteristics of the subjects are reported in Table 1. A total of 41 subjects were assigned to educational control and 40 to intervention. Three intervention subjects withdrew before completing the intervention; all others completed a minimum of five intervention visits. An additional three subjects (two control subjects and one intervention) withdrew before the 6-month follow-up. Subject retention was 96% at the postintervention follow-up and 93% at the 6-month follow-up. A1C data were available for 78 participants (38 intervention and 40 control subjects) during the short-term follow-up window and 73 (36 intervention and 37 control subjects) during the 1-year follow-up window. No subjects changed insulin delivery from injection to pump or vice versa during the study.

Goals selected by youth represented key diabetes management tasks, including blood glucose monitoring (22%), physical activity (22%), dietary management (19%), record keeping (19%), insulin administration (8%), management of out-of-range blood glucose (6%), and parent-child communication (3%). Approximately half of the youth developed a second personal plan; goals included blood glucose monitoring (38%), dietary management (25%), insulin administration (19%), physical activity (13%), and management of out-of-range blood glucose (6%).

At short-term follow-up, youth in the control group showed a 4.15 increase from baseline in A1C percent over normal (0.25 increase in actual A1C value), while those in the intervention group had a 4.76 decrease (0.29 decrease in actual value). Results of the ANCOVA, adjusting for age and baseline A1C, indicated a trend for an overall intervention effect ($F = 3.71$, $P = 0.06$) and a significant intervention-by-age interaction, indicating a greater effect among older than younger youth ($F = 4.78$, $P = 0.03$) (Table 2). Stratified analyses run with younger (aged 11–13 years, $n = 42$) and older (aged 14–16 years, $n = 36$) youth indicated a significant positive intervention effect for the latter only ($P = 0.02$). For the older youth, those in the control group increased A1C percent over normal 7.10 from baseline (0.43 increase in actual A1C value), while those in the intervention group decreased 8.75 (0.53 decrease in actual A1C value).

At 1-year follow-up, youth in the control group had a mean A1C percent over normal 6.57 greater than baseline (0.40 increase in actual A1C value), while the intervention group's mean A1C percent over normal was 0.19 less than baseline (0.04 decrease in actual A1C value). ANCOVA results indicated a trend for a main intervention effect on A1C ($F = 3.79$, $P = 0.06$) and a significant intervention-by-age interaction ($F = 4.53$, $P = 0.04$), indicating a greater effect among older youth (Table 2). Subgroup analyses indicated a trend for an intervention effect for the older youth. Among these youth, those in the control group increased A1C percent over normal 10.11 from baseline (0.62 increase in actual A1C value), while those in the intervention group decreased 4.00 (0.25 decrease in actual A1C value).

There were no differences between groups on parent report of adherence at short-term or 1-year follow-up (Table 2). There was a trend toward worse youth report of adherence at short-term follow-up but no difference at 1-year follow-up. No intervention-by-age interaction was observed for adherence at either time period. No differences between groups at short-term follow-up occurred for self-efficacy, positive outcome expectations, or negative outcome expectations (Table 2). At 1-year follow-up, however, youth in the intervention group reported lower positive outcome expectations. In addition, youth in the intervention group reported higher diabetes impact but no differences on worry or satisfaction quality-of-life scales.

Both youth and parents reported high satisfaction with the program, with mean responses to individual satisfaction items (6-point scale) ranging from 4.71 to 5.89 for youth (overall mean = 5.32) and from 4.75 to 5.68 for parents (overall mean = 5.34). One-hundred percent of families indicated that they would recommend the program to others. When asked what they liked best about the program, most youth reported that they liked setting, working on, and achieving a specific goal. Parents appreciated their child having someone to talk with about diabetes other than themselves. Some noted that the child told the personal trainer about problems they had not previously shared with the parent, and one parent noted that the child was more willing to try new solutions with the personal trainer. Parents also liked the individual attention the child received. One parent described liking this "different approach to managing diabetes," one that involved identifying problems, developing solutions, and monitoring progress. When asked to describe what they liked least about the program and how it could be improved, the most common response from both youth and parents was "nothing." However, several parents reported desiring more involvement in the program or a more clearly defined role. Many youth and parents also indicated that they would have liked the program to be of longer duration. Overall, both youth and parents indicated appreciation of the personal trainers, providing comments such as "this helped me a lot, thank you" and "my personal trainer was more than excellent; she was spectacular" (youth), as well as "let's do it again!," "thank you, thank you!," "trainer was outstanding," and "loved our trainer" (parents).

CONCLUSIONS

Findings indicate that a behavioral self-regulation intervention is a promising approach for preventing the decline in blood glucose control that typically occurs during adolescence. However, this intervention effect occurred specifically among middle adolescents and not among pre-/early adolescents. An intervention-by-age interaction remained significant at both time points, indicating persistent positive treatment effects among the middle adolescents. The magnitude of difference in glycemic control between treatment groups among middle adolescents was substantial and clinically meaningful. Maintenance of differences of this magnitude could have significant effects on the long-term health consequences of diabetes (7,34,35).

There are several possible explanations for these differing outcomes by age. The poorer management typical of older youth might provide greater opportunity for intervention effects. The majority of the youth in this study were on insulin pump regimens, and overall baseline A1C was somewhat lower than might be expected in a sample of youth this age (1). As such, the potential for short-term improvement is minimized, particularly among the younger participants. It is also possible that the design of the intervention was more appropriate for middle adolescents; a youth-focused intervention may not show effects until the children achieve more autonomy in their diabetes management (36). A more active engagement of parents and facilitation of parent-child cooperation may be needed to achieve an effect during early adolescence. Parent response to the program also indicated that this would be desirable.

The finding of a trend toward lower child-reported adherence at short-term follow-up is concerning but does not correspond to the observed decrease in A1C. Typically, the relationships between adherence and A1C has been modest at best (e.g., 30). Moreover, no group differences occurred in parent report of adherence. It is plausible that exposure to the intervention, which included a self-monitoring component, resulted in greater awareness of behavior and less tendency to overestimate adherence. Our finding of positive intervention effects on A1C, but not on adherence, is noteworthy, since the hypothesized effect of this behavioral intervention on A1C is one mediated by adherence behaviors.

Contrary to our hypotheses, there were no group differences on the hypothesized mediators of self-efficacy and outcome expectations at short-term follow-up. Moreover, a significant negative effect was observed on positive outcome expectations at 1-year follow-up. Similarly, the intervention group reported higher diabetes impact at 1-year follow-up. As with the assessment of adherence, it is possible that more objective self-monitoring of one’s actual adherence behaviors during the intervention might have had a negative effect on subsequent cognitive appraisals, especially given the increase in diabetes management difficulty that is common during adolescence.

A strength of this study is its relatively large sample, including youth from two clinical practices with multiple pediatric endocrinologists serving multistate urban, suburban, and rural populations. The resulting sample was similar to the ethnic distribution of type 1 diabetes, with 15% minorities and youth from both low and high socioeconomic status families. It should be noted that we were unable to control for the amount of personal trainer attention by providing similar levels of attention in the control group. However, in previous studies of behavioral interventions (e.g., 37), “attention control” conditions have consistently failed to yield clinically or statistically significant treatment effects. Another weakness of the study is that we did not assess problem-solving skills, which may have been an important mediator. However, existing measures of problem solving are primarily advanced measures of diabetes knowledge and do not adequately assess the process of problem solving. Feedback from the intervention staff suggested that problem-solving processes were salient to youth as they used their personal plans to work on the identified goals.

While the approach tested in this study demonstrated efficacy for improving glycemic control, it must be noted that practical difficulties would hinder large-scale implementation, particularly the lengthy distances often traveled by staff. Many families also indicated a desire for the program of longer duration. As such, adaptation of the approach would be needed to enhance feasibility, translatability, and potential cost-effectiveness. However, since the approach was not dependent on delivery in the home environment, it is likely that its effectiveness would not be impaired by adaptation to the clinical or other environment.

Findings from this study support the utility of trained nonprofessionals as interventionists. The personal trainers demonstrated fidelity to the intervention and adequate delivery of skills. Qualitative feedback indicated that the youth and their parents were enthusiastic about the program and the personal trainers. Families voiced appreciation of both the relationship with the personal trainer and helpfulness of the intervention process. Their enthusiasm for the program is notable given the reality that they sometimes had difficulty finding time to schedule the intervention visits. Children were responsive to the motivational interviewing interaction style, had no difficulty identifying areas of diabetes management that they would like to improve, and actively engaged in the behavior-change process. Importantly, the outcomes suggest that self-management skills are a relevant and important target for improving blood glucose control during adolescence.

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Table 1

Sample demographics

	Control*	Intervention*	Total
n	41	40	81
Child characteristics			
Age (years)	13.9 ± 1.6	13.6 ± 1.9	13.8 ± 1.7
Sex			
Female	22 (53.7)	23 (57.5)	45 (55.6)
Male	19 (46.3)	17 (42.5)	36 (44.4)
Race/ethnicity			
Black	5 (12.2)	4 (10.0)	9 (11.1)
White	36 (87.8)	33 (82.5)	69 (85.2)
Other	0 (0.0)	3 (7.5)	3 (3.7)
Duration of diabetes (years)	7.8 ± 4.0	7.5 ± 3.4	7.7 ± 3.7
Regimen			
Multiple daily injections	14 (34.1)	16 (40.0)	30 (37.0)
Insulin pump	27 (65.9)	24 (60.0)	51 (63.0)
A1C at baseline (percent above upper limit of normal)			
Age 11–13 years	42.2 (28.6)	46.3 (34.1)	44.3 (31.3)
Age 14–16 years	35.9 (20.7)	40.4 (24.5)	38.2 (22.6)
	48.6 (34.1)	53.6 (42.7)	51.0 (38.0)
Parent characteristics			
Relationship to child			
Mother/stepmother	34 (82.9)	33 (82.5)	67 (82.7)
Father/stepfather	7 (17.1)	7 (17.5)	14 (17.3)
Number adults in home			
1	8 (19.5)	8 (20.0)	16 (19.8)
2	29 (70.7)	31 (77.5)	60 (74.1)
≥3	4 (9.8)	1 (2.5)	5 (6.2)
Parent race/ethnicity			
Black	5 (12.2)	4 (10.0)	9 (11.1)
White	36 (87.8)	35 (87.5)	71 (87.7)
Other	0 (0.0)	1 (2.5)	1 (1.2)
Education level of mother			
High school or less	6 (15.0)	9 (23.1)	15 (19.0)
Some college or technical degree	11 (27.5)	12 (30.8)	23 (29.1)
College degree or higher	23 (57.5)	18 (46.2)	41 (51.9)
Education level of father			
High school or less	6 (16.7)	5 (14.7)	11 (15.7)
Some college or technical degree	8 (22.2)	13 (38.2)	21 (30.0)
College degree or higher	22 (61.1)	16 (47.1)	38 (54.3)
Household income			
<$30,000	7 (17.9)	6 (15.4)	13 (16.7)
$30,000 to $49,999	5 (12.8)	2 (5.1)	7 (9.0)
$50,000 to $99,999	13 (33.3)	16 (41.0)	29 (37.2)
≥$100,000	14 (35.9)	15 (38.5)	29 (37.2)

Data are means ± SD or *n* (%).

* No significant differences were observed between groups on any of the demographic variables.

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Table 2

ANCOVA treatment group effects with age and baseline values of each outcome as covariates, treatment group means adjusted for age and baseline values, and intent-to-treat analyses

	Short-term follow-up			1-year follow-up		
	Control	**Intervention**	***P***	**Control**	**Intervention**	***P***
Metabolic control						
A1C percent above upper limit of normal	46.77 ± 2.64	39.58 ± 2.71	0.06	50.28 ± 3.50	43.68 ± 3.50	0.06
A1C by age interaction	—	—	0.03	—	—	0.04
Metabolic control (stratified analysis)						
Age 11–13 years A1C percent above upper limit of normal	38.16 ± 3.56	37.49 ± 3.39	0.89	40.62 ± 4.23	42.71 ± 4.12	0.73
Age 14–16 years A1C percent above upper limit of normal	56.91 ± 3.89	42.30 ± 4.35	0.02	61.06 ± 5.64	45.21 ± 5.81	0.06
Adherence						
Parent report of adherence	0.65 ± 0.01	0.65 ± 0.01	0.97	0.62 ± 0.01	0.63 ± 0.01	0.76
Child report of adherence	0.66 ± 0.01	0.63 ± 0.01	0.06	0.63 ± 0.02	0.62 ± 0.02	0.47
Beliefs						
Self-efficacy	8.16 ± 0.16	7.82 ± 0.16	0.14	7.73 ± 0.25	7.50 ± 0.26	0.52
Positive outcome expectations	6.45 ± 0.26	6.43 ± 0.27	0.96	6.87 ± 0.26	6.11 ± 0.27	0.05
Negative outcome expectations	8.10 ± 0.17	7.81 ± 0.18	0.26	7.67 ± 0.29	6.96 ± 0.30	0.09
Quality of life						
Impact	—	—	—	41.37 ± 1.27	45.04 ± 1.33	0.05
Worry	—	—	—	19.62 ± 0.86	18.93 ± 0.90	0.58
Satisfaction	—	—	—	65.88 ± 1.96	66.45 ± 2.05	0.84

Data are adjusted means ± SE. ANCOVA treatment group effects with age and baseline values of each outcome as covariates, treatment group means adjusted for age and baseline values, and intent-to-treat analyses.