

Randomized Clinical Trial of Clinic-Integrated, Low-Intensity Treatment to Prevent Deterioration of Disease Care in Adolescents With Type 1 Diabetes

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OBJECTIVE

To evaluate the efficacy of two office-based treatments designed to prevent deterioration in glycemic control in young adolescents with type 1 diabetes in a randomized clinical trial. An individualized, more intensive family teamwork Coping skills program was compared with a diabetes Education treatment.

RESEARCH DESIGN AND METHODS

A baseline assessment was followed by four brief treatment sessions and immediate posttesting over the course of 1.5 years. Families of 226 early adolescents (ages 11–14) were randomized to receive either individualized coping skills education or diabetes education as adjunctive treatment to quarterly medical appointments. Continued follow-up occurred at 3.5-month intervals for a longterm follow-up of up to 3 years. A post hoc Usual Care group facilitated comparisons of glycemic control.

RESULTS

Growth curve analysis showed that both treatment groups successfully prevented deterioration in adolescent disease care and simultaneously improved adolescent and parent quality of life that included indicators of more effective communication and reduced adherence barriers—without a concomitant increase in diabetes-related or general family conflict. However, contrary to expectation, the Education group was more efficacious than the Coping group in improvement of disease adherence and glycemic control over a 3-year follow-up.

CONCLUSIONS

Low-intensity office-based quarterly treatment can maintain or improve disease care adherence in early adolescence when provided to adolescent/parent dyads. Better outcomes are achieved when treatment goals and techniques match the needs of the targeted population.

Behavioral and family factors coalesce in adolescence to make disease management particularly challenging in type 1 diabetes with a transition from parent- to youth-initiated care and with adolescent strivings for autonomy and increased family conflict (1–6). Typically, diabetes care and glycemic control deteriorate throughout adolescence as parents increasingly disengage from care. Poorer adolescent

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© 2014 by the American Diabetes Association. See http://creativecommons.org/licenses/bync-nd/3.0/ for details. management, once established, often persists into young adulthood (7,8). Efforts to sustain effective diabetes care from late childhood through adolescence and to prevent deterioration in care could yield lasting and significant individual and public health benefits.

Parental monitoring of adolescent disease care contributes to better youth adherence and to better glycemic control (9,10) but can be associated with counterproductive family conflict (11-13). The dual dilemma of diabetes care deterioration and increased conflict during adolescence is well recognized and has precipitated intervention efforts by Anderson et al. (13), Laffel et al. (14), and Wysocki et al. (12) that focus on more effective communication to offset increased conflict and decreased adherence (12,13). Treatment studies generally adopt either a "prevention" orientation that seeks to avoid deterioration in care and increased conflict or an "intervention" focus to rectify problems once present. Prevention programs usually deliver a relatively smaller dose of uniform treatment to inoculate all pediatric patients within a given age range. Treatment sessions are relatively few, four or five, and usually brief (20-25 min) adjunctive meetings to quarterly medical appointments (13,14). These low-intensity features of clinic-integrated prevention programs are more translatable into routine care, since specialized psychological expertise is not required to identify, target, and treat individual "cases." More complete descriptions of these programs have previously been published (13,14). In contrast, intervention programs typically are more intensive and selectively directed toward youth and families with identified problems—usually, poorer adherence or glycemic control. Sessions are more frequent, such as weekly or bimonthly; lengthier (often an hour); and focus more intensively on individual and family processes deemed counterproductive to optimal disease care and family functioning (15,16). Intervention treatment also has been used preventatively, for example, by Grey and colleagues (17,18) to facilitate the introduction of intensive insulin therapy. However, intensive elements of intervention programs limit their ready adoption into routine clinical care. More comprehensive descriptions of these

programs have previously been published (15,17–19).

The current randomized clinical trial (RCT) sought to combine the optimal components of a prevention treatment approach (13) with the benefits of a brief intervention program of coping skills (17) to help early adolescents avoid deterioration in disease care and glycemic control. Prevention features included brief quarterly treatment sessions with adolescent/parent dyads as an adjunct to medical appointments and enrollment of all young adolescents, regardless of most preexisting problems. For an increased dose of treatment compared with a standardized education treatment, a more intensive coping skills program was provided via individualized dyadic instruction designed to sustain parental monitoring without an increase in conflict.

The efficacy of a family teamwork coping program versus a psychologically supportive education program to maintain parental involvement and disease care throughout early adolescence was evaluated in this RCT. Specifically, more sustained parental monitoring and disease care was hypothesized from baseline through follow-up for a coping versus an education comparison group without an accompanying increase in family conflict. Further, sustained or increased self-efficacy for diabetes management was expected with individualized coping treatment administered to parent/youth dyads. Based on the universal coping skills taught, the Coping group was hypothesized to have more sustained long-term follow-up. Finally, efficacy of the two treatments to mitigate adolescent deterioration in glycemic control was evaluated. Glycemic status of study participants was compared with that of a post hoc Usual Care (UC) group of adolescents. Participants in both treatment groups were projected to show less glycemic deterioration over time than a group of adolescents in UC.

RESEARCH DESIGN AND METHODS Participants

Eligibility requirements were youth age 11–14 years, disease duration >1 year, absence of severe medical/psychiatric complications, and English fluency. Youths were recruited without regard to glycemic control. Participants were 226 family dyads composed of one parent (92% mothers) and youth with type 1 diabetes. The same parent who started the study was requested to complete each treatment session and all assessments. Other parent caregivers were invited to participate, but few did. See Table 1 for sample characteristics.

Procedure

Participants attended diabetes clinics at two children's hospitals. Eligible families were contacted by letter and a follow-up telephone call. Written consent and assent were obtained. All study components were conducted at scheduled quarterly endocrinology appointments. Baseline and follow-up data consisted of self-report questionnaires completed separately by parents and adolescents. Medical data were corroborated via chart review. Assessments required 45–60 min; families received gift cards in the amount of 25 USD at baseline.

The treatment program included four brief quarterly coping skills or diabetes

Table 1—Participant disease and demographic characteristics				
	Education	Coping		
Ν	89	137		
Youth age (years)	12.73 ± 1.23	12.95 ± 1.24		
Diabetes duration (years)	5.15 ± 3.16	4.93 ± 2.95		
Youth sex, % female	46.1	55.5		
Family structure, % unmarried	22.7	23.7		
Youth ethnicity, % nonwhite	24.7	32.1		
Hollingshead SES score	48.70 ± 11.0	46.22 ± 11.22		
Insulin regimen, %				
Pump	48.3	45.3		
Lantus	31.5	29.2		
Regular plus NPH	20.2	24.8		

educational sessions with one parent and youth, conducted before/after a medical appointment. Sessions began ~3.5 months after baseline assessment. Immediately after the fourth treatment session, quarterly follow-up assessments occurred for a maximum of 1.5 years after treatment completion or for a total of six possible assessments over the 3-year course of the study. Remuneration was 65 USD/follow-up assessment.

Power analysis indicated an N of 170 was necessary to detect a medium effect size between the Coping and Education groups with latent growth curve analysis (GCA) (20). To account for anticipated attrition of 5–10% over the course of treatment, an N of at least 190 was sought. Of 395 eligible families

successfully contacted, 281 consented to participate. Complete baseline data were provided by 257 dyads (90%). Baseline run-in failures that were not randomized cited a lack of interest or time to continue the study. Randomized participants (88%) were assigned in approximately a 1.5:1 ratio to coping or education treatment. Randomization, block stratified by HbA_{1c} levels above and below 8.2% (66 mmol/mol), ensured that groups had equivalent proportions of participants with higher and lower HbA_{1c} values. See Fig. 1 for participant flow through the study. Most families completed the immediate posttest (95%), but only those enrolled earlier in the study could attain the 6th assessment (60%) for long-term 3-year follow-up.

UC

 HbA_{1c} levels from a group of UC adolescents (N = 205) were obtained post hoc from medical charts to provide a comparison of the natural course of glycemic status during adolescence. Youth in the UC group were within the same age range as that of randomized youth during time of study enrollment (2007–2010) and were proportionally drawn from each study site. UC participants did not actively participate in the current study assessments and were not randomized to the UC condition.

Appropriate institutional review boards approved both the original study and this post hoc study component.

Prevention Programs

The family teamwork coping program was designed to facilitate diabetes

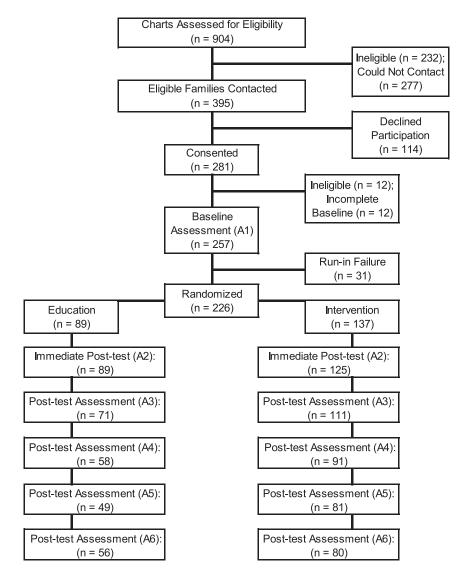


Figure 1—Consolidated Standards of Reporting Trials (CONSORT) diagram with the participant flow through recruitment, randomization, and progress through the study.

management and to promote effective family interactions. The Coping group focused on developmental challenges surrounding the diabetes regimen with formal discussion and practice of coping skills (18) such as attitude and behavior change. Coping skills were discussed and practiced at four quarterly 30- to 45-min modules over a year. The first session included information about puberty, authoritative parenting, and the need for effective adolescent/parent communication. Treatment was individualized by eliciting areas of potential family concern surrounding a diabetes task or a coping skill, e.g., blood glucose monitoring or communication, with brief family practice plans designed to incorporate family input and to facilitate more effective coping with problems between visits. Other sessions included problem solving regarding blood glucose monitoring, conflict resolution surrounding dietary issues, and parental support and cognitive reframing to promote exercise (13,19).

Graduate-level interventionists led the coping sessions with parent/youth dyads and were unknown to study participants prior to study start. A 2-day training workshop for interventionists occurred at study initiation followed by a 1-day refresher a year later. Coping sessions consisted of a brief introduction of family teamwork or a review of the previous session's content, information relevant to new content area. or an activity related to a new area and development of a behavioral practice plan. Sessions stressed continued parental involvement (21). Active listening and open communication were modeled throughout, as were problem solving, conflict resolution, and cognitive reframing. After each session, families received a brochure of major session points along with an individualized practice plan developed during the session for home use. A follow-up telephone call 1 month later reviewed plan implementation and made modifications as needed.

The diabetes education sessions were led by BA-level facilitators who met with parent/youth dyads at four quarterly consecutive appointments for a year. Education facilitators were unknown to study participants prior to the study start. Facilitators had knowledge of pediatric diabetes and

experience with families; facilitators received supervised training and monitoring throughout the course of the study. Sessions were 15-20 min and consisted of ice-breaking social questions and the following diabetes content: communication about diabetes, diabetes and extracurricular activities, travel, and school issues that included 504 education plans and diabetes rights. After each completed session, education families received a brochure of the major session points. No discussion of parental involvement, authoritative parenting, or practice plans occurred. Education content was uniform—not individualized—and no patient contact occurred between sessions.

Treatment Fidelity

Both coping and education sessions were audio recorded for treatment fidelity. Each month, 25% of sessions were selected for fidelity checks across different interventionists/facilitators. A study coordinator and principal investigator established adequate interrater reliabilities (\geq 80%). Content fidelity of \geq 80% per session was required; otherwise, interventionist/facilitator retraining occurred.

Measures

Background Information

Demographic and medical information was obtained, and socioeconomic status (SES) was assessed; higher Hollingshead scores indicate higher SES (22).

Glycemic Control

Measurement of HbA_{1c} used the same technology at each study site (DCA 2000, reference range 4.3–5.7% [23–39 mmol/mol]; Bayer, Tarrytown, NY). This technology produces results comparable to those of central laboratory assays with only minimal, expected variations between sites (23).

Diabetes Adherence

The Diabetes Behavior Rating Scale (24) assessed management of disease care over the previous week via a questionnaire. Total scores were analyzed. The Diabetes Behavior Rating Scale scores reflect frequency of routine diabetes care behaviors. Adequate internal consistency is published for the test normative pump/injection versions (both forms, parent = 0.84; both forms, youth = 0.84) and in the baseline scores of the current sample (pump/injection, parent = 0.76/0.79; pump/injection, youth 0.79/0.82).

Parental Monitoring

The Parental Monitoring of Diabetes Care scale (16,25) measured parental monitoring of youths' diabetes behaviors and adherence. Higher scores indicate more parental monitoring. Total scores were analyzed. Published data reveal adequate internal consistency (parent = -0.81; youth = 0.79). Fair consistency was found in the baseline scores of the current sample (parent/ youth = 0.75)

Parents only completed the Outcome Expectations of Parental Involvement scale (26) to assess beliefs about the effectiveness of parental monitoring and its effects on adolescents. Sample items included "I can teach my child how to handle any problems or difficulties that come up" and "My child will think I'm prying into his/her business." Total scores were analyzed. Adequate consistency is noted in the test normative sample (0.84) and in the current sample at baseline (0.80).

Family Conflict

The Diabetes Family Conflict Scale-Revised (27) assessed diabetes-specific conflict. Total scores were analyzed. Adequate internal consistency is found in the scores of the normative sample (youth = 0.85/parent = 0.81) and in the study sample (youth = 0.96/parent = 0.89). The conflict subscale of the Family Environment Scale (28) measured general family conflict. Total scores were analyzed, which showed fair normative internal consistency (parent/ youth = 0.75) and sample consistency (parent = 0.76/youth = 0.71). Higher scores on each measure indicate higher conflict.

Self-Efficacy

The Self-Efficacy for Diabetes Self-Management scale (26) assessed an adolescent's and a parent's perceived self-efficacy to perform diabetes care behaviors. Total scores were analyzed, which demonstrated adequate consistency in the normative (parent/youth = 0.90) and current sample at baseline (parent/youth = 0.85).

Diabetes Quality of Life

The Pediatric Quality of Life–Diabetes subscales (29) assessed youth/parentproxy report of a youth's diabetes quality of life. Items are reversed scored; higher scores always reflect better quality of life. Total scores were analyzed. Adequate internal consistency is found in the standardization sample (parent/youth = 0.85) and in the study sample at baseline (parent/youth = 0.81).

Statistical Analysis

Individual GCA (32) evaluated the effects of Coping versus Education treatment on trajectories of study outcomes from baseline to final assessment ~3 years later. A third (UC) comparison group was included only for the analysis of glycemic control (HbA_{1c}). GCA time intervals were recorded in years. Four steps compared group main effects and rate of outcome change, with the latter depicted as an interaction term to reflect outcome change over time. First, linearity of each outcome trajectory was examined with time and time squared as independent variables. A nonsignificant squared term indicates a linear trajectory. Second, an unconditional model with only time as an independent variable evaluated changes in trajectory over time. Third, a conditional model evaluated Group and Year as independent variables. A significant group coefficient indicates group differences in level of outcome from baseline to the last follow-up. The final step added a Group imes Year interaction term as an independent variable to test group differences in rate of change for each outcome. Since SES is a significant factor related to most major outcomes in this clinical trial, SES was used as a covariate in all conditional models to minimize slight group differences (33).

RESULTS

Demographic Features

Descriptive statistics are presented in Table 1. The Coping group (N = 137) and Education group (N = 89) were randomly assigned such that no group differences were found at baseline in youth age, disease duration, and SES with independent t tests. χ^2 analyses revealed no group differences in sex, family structure, ethnicity, or insulin regimen. Depending on time of enrollment, not all participants had the opportunity to progress to 3-year follow-up. SES of each group at each time point was comparable with one another at baseline and at every follow-up assessment such that groups at study end were demographically representative of the baseline groups (SES group variation over 3 years 46.8–50.2).

HbA_{1c}

ANOVA indicated that baseline HbA_{1c} levels did not differ among the three study groups (Coping, Education, and UC). Figure 2 shows observed and regressed fitted GCA values of HbA_{1c} for the two treatment groups and the UC HbA_{1c} comparison group over time. Visual inspection shows that HbA1c increased for the Coping and UC groups but decreased for the Education group. Overall. GCA shows that the difference in HbA_{1c} levels for the three groups did not reach significance; however, the rate of change in HbA_{1c} over time was significantly better for the Education versus UC group (P < 0.01) and for the Education versus Coping group (P =0.05); i.e., glycemic control improved in the Education group over time compared with the other two groups. The HbA_{1c} of the Coping and UC groups did not differ from one another.

Psychosocial Assessments

Only the Coping and Education treatment groups received the psychosocial assessments. Adolescent and parent scores showed high concordance rates on all of the psychosocial study variables; youth scores consistently were higher regardless of the dimension assessed. Scores were averaged for analysis to achieve greater parsimony, stability, and retention of input from each data source. In the case of dual assessments completed by two caregivers (N = 5), maternal reports were analyzed in a manner consistent with the analysis of the majority of data from other participants.

Independent *t* tests showed that treatment groups did not differ in any of the psychosocial or disease-management study variables at baseline. GCA was used to evaluate treatment effects on diabetes adherence, parent monitoring, quality of life, and self-efficacy. Adherence behavior outcomes are presented in Fig. 2. Visual inspection reveals that the Education group performed better than the Coping group. The Education group improved in diabetes adherence across all follow-ups (P = 0.014) and improved more over time (P = 0.011) relative to the Coping group. In contrast, the Coping group demonstrated sustained diabetes adherence that did not deteriorate over time. Both groups showed lower levels of parental monitoring over time (Fig. 3), although the Education group tended to have more parental monitoring than the Coping group over time. Both treatment groups had positive parental expectations about involvement (Outcome Expectations of Parental Involvement scale) that remained similarly high through the study (not shown). Group scores also remained similar for both diabetes-related and general family conflict from study beginning to end (not shown). GCA revealed that self-efficacy did not change during the study (Fig. 3). GCA indicates that both groups improved similarly in quality of life over time (Fig. 3).

CONCLUSIONS

Two family-based clinic-integrated prevention programs were efficacious and helped young adolescents with type 1 diabetes prevent deterioration in disease care behaviors. Participants in this RCT were assigned to either a family teamwork Coping group or a diabetes Education comparison group. Each treatment consisted of four sessions with adolescent/parent dyads over the course of a year as an adjunct to quarterly medical appointments. Both groups successfully prevented deterioration in diabetes management behaviors and showed improvements over time in quality of life. Further, parents in both groups maintained their initial positive beliefs about the importance of parental monitoring, although monitoring decreased throughout the study, perhaps reflecting improved quality of life that occurred during the study or the natural tapering of parental monitoring that occurs with older adolescent age. Equally importantly, both parents and youth sustained feelings of self-efficacy for diabetes management during treatment despite behavioral and hormonal changes in early adolescence, ages 11-14 years, which can disrupt diabetes care and glycemic control (3).

Contrary to expectation, the diabetes education comparison group performed

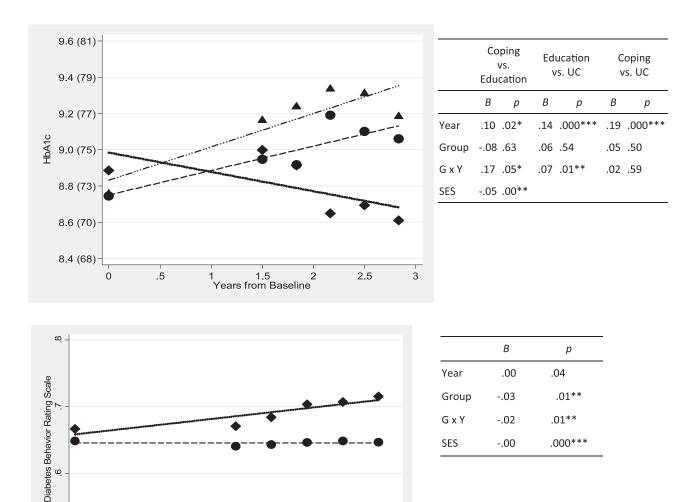


Figure 2—Developmental trajectories of HbA_{1c} (*top*) for the Coping, Education, and UC groups from baseline to the 6th assessment. Note that IFCC values are in parentheses. Developmental trajectories of adherence (*bottom*) for the Coping and Education groups only from baseline to the 6th assessment. G x Y, Group by Year interaction; $*P \le .05$; $**P \le .01$; $***P \le .001$; dashed line, Coping; \bullet , Coping observed values; dotted line, Education; \blacklozenge , Education observed values; dash line with three dots, UC (*top* only); \blacktriangle , UC observed values (*top* only).

2.5

3

as well or better than the teamwork Coping group on study outcomes. Importantly, disease adherence was maintained during this high-risk developmental transition as hypothesized for the Coping group, but disease adherence improved in the Education group (Fig. 2). Both groups started the study with similar adherence scores at the lower end of the normative range (23). Unexpectedly, the Education group alone improved disease care scores over time and more closely approximated the test standardization sample by study end. As hypothesized, disease care did not deteriorate in the Coping group, but neither did it improve like in the Education group. Consistent

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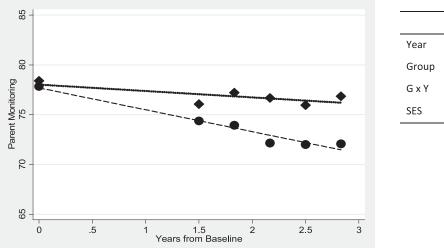
Years from Baseline

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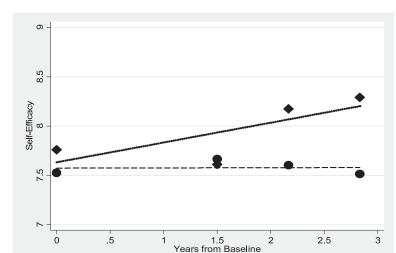
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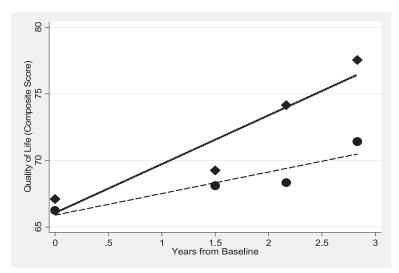
with adherence findings, the Education group alone improved in glycemic control from study start to finish (HbA_{1c} 8.89-8.61% [74 to 71 mmol/mol]) (See Fig. 2). The Coping group generally sustained HbA_{1c} values over the study as hypothesized but did not do better than the UC group, who had a similar but slightly higher elevation in HbA_{1c} slope. Importantly, sustained adherence (Coping group) or improved adherence (Education group) occurred without increased diabetes-related or family conflict. The Education group performed as well or better than the Coping group in quality of life and other study outcomes, contrary to expectation. The common session format of parent/youth dyadic instruction appeared to facilitate family interaction, communication, and diabetes teamwork without an increase in conflict, regardless of treatment. However, study groups differed appreciably in the focus and participant demands of sessions. The coping sessions had a problem and process focus on identification of disease management concerns to facilitate individualization of coping skill instruction and development of diabetes practice plans. In contrast, the Education group received uniform information that was practical, if sometimes rudimentary, in a straightforward manner that was more efficient and focused on



	В	p
Year	-1.92	.000***
Group	-1.19	.22
G x Y	50	.31
SES	01	.78



	В	p
Year	.03	.38
Group	12	.39
G x Y	02	.79
SES	.03	.000***



	В	p
Year	1.72	.001**
Group	35	.82
G x Y	31	.63
SES	.21	.001**

Figure 3—Developmental trajectories of parent monitoring (*top*), self-efficacy (*middle*), and quality of life (*bottom*) for the Coping and Education groups from baseline to the 6th assessment. G x Y, Group by Year interaction; $**P \le .01$; $***P \le .001$; dashed line, Coping; \bullet , Coping observed values; dotted line, Education; \bullet , Education observed values.

the information itself and not on the process of coping skill acquisition, which may have better aligned with the disease-specific study outcomes. Further, the individualization and problem focus of the Coping group sometimes elicited negative emotions, and its process orientation resulted in longer sessions than the briefer, neutral, and more focused exchanges of education information. Higher attrition in the Coping (9%) versus Education (0%) group at immediate follow-up may reflect these focus and process differences, although on average youth and parents in the Coping group felt that they learned more (4.0 on a 5-point scale) than the Education group (3.5 on a 5-point scale).

In keeping with the broad-based prevention goal of the study, adolescents and parents were recruited regardless of level of disease care or glycemic control. All participants were told they would learn methods to promote disease management and to prevent problems as youth transitioned into adolescence. The straightforward presentation of education information may have better matched participant expectations and needs, since many subjects did not report problems. Beyond participant expectations, the general lack of participant demands in the Education group may have better aligned with the low-intensity delivery of information at quarterly appointments. Additionally, with average diabetes duration of 5 years, most youth in the current study were 7 years old when diagnosed. Education may be particularly germane for youth 5 years after diagnosis. Although reeducation of youth after diagnosis is routinely recommended (34), it does not appear to be routinely implemented. Education may be particularly salient with transition into formal cognitive operations; abstraction skills can aid better understanding of diabetes information.

Beyond this prevention study, intervention studies that target youth in poorer glycemic control also find that diabetes education yields favorable outcomes. One small RCT used motivational interviewing (MI) or education to enhance diabetes care and improve poorer glycemic control (HbA_{1c} >9% [73 mmol/mol]) in adolescents hypothesized to lack motivation for more effective care. However, glycemic control of the MI adolescents actually deteriorated during the study versus that of an Education group that improved (35). Wysocki et al. (15) treated small groups of families who received 12 bimonthly sessions of American Diabetes Association-recommended education curricula versus more intensive individualized Behavioral Family Systems Therapy–Diabetes. Education improved communication, family interactions, adherence, and glycemic control, even though the Education group was not taught communication or conflict resolution skills. Interestingly, Grey et al. (36) have successfully adapted both coping and education sessions to an online delivery format.

In the current study, four quarterly coping sessions sustained disease adherence over 3 years, consistent with other problem-solving family teamwork programs with similar low-intensity delivery schedules (13). However, consistent with others, the current study also did not yield clear-cut improvements in glycemic control with coping skills treatment. Despite the greater formal education and skills of the coping interventionists and the lengthier coping treatment sessions, the Coping group nevertheless was less efficacious and less cost-effective than the Education group in effecting desirable diabetes outcomes. Also noteworthy, universally applicable coping skills were hypothesized to enhance more consistent generalization of treatment gains over time. However, 3-year follow-up favored the Education group. Accumulating evidence in this and other studies suggests that participants in prevention studies may have less need for individualized coping skill sessions and concomitantly have less "room" to improve glycemic control; i.e., regression to the mean is less striking with less distance from the mean in better functioning youth. Ideally, careful alignment of treatment goals, participant characteristics, session demands, and delivery schedule should optimize treatment efficacy.

In sum, adolescent/parent dyadic education sessions in the current study appeared to better align with the lowintensity broad-based prevention goal of this study than the coping skills sessions. Further, dyadic family (37-39) education sessions were briefer, standardized, and administered by less specialized facilitators; hence, they likely would be more cost-effective as well as more efficacious than coping instruction in a clinical setting. In essence, the coping sessions may have constituted "overtreatment" or treatment mismatched to the recruitment audience and session delivery schedule. Many middle-class families simply may not require the extra content and skill building that the coping sessions incorporated in order to sustain disease adherence and prevent conflict. Alternatively, coping skill training may prove more efficacious at earlier ages, perhaps 9-11 years, to facilitate an unfettered focus on skill acquisition itself before the onset of adolescence. Finally, although the present sample was ethnically diverse, these findings should be weighed in light of the primarily middle-class sample that participated in this prevention study. Use of a randomized UC group also should be considered to enhance future research in this area.

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Duality of Interest. No potential conflicts of interest relevant to this study were reported.

Author Contributions. C.S.H. wrote the manuscript, researched data, and was the principal investigator. R.C. conducted the statistical analyses and reviewed and edited the manuscript. E.M. helped write the manuscript, researched data, and reviewed and edited the manuscript. M.G. collaborated with coping skill instruction and reviewed and edited the manuscript. R.S. researched data, served as site principal investigator, and reviewed and edited the manuscript. C.S.H. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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