Behavior Therapy for Families of Adolescents With Diabetes

Maintenance of treatment effects

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OBJECTIVE — This study reports 6- and 12-month follow-up for the families of adolescents with diabetes who participated in a trial of Behavioral–Family Systems Therapy (BFST).

RESEARCH DESIGN AND METHODS — A total of 119 families of adolescents with type 1 diabetes were randomized to 3 months of treatment with either BFST, an education and support (ES) group, or current therapy (CT). Family relationships, adjustment to diabetes, treatment adherence, and diabetic control were assessed at baseline, after 3 months of treatment, and 6 and 12 months later. This report focuses on the latter two evaluations.

RESULTS — Compared with CT and ES, BFST yielded lasting improvements in parent-adolescent relationships and diabetes-specific conflict. Delayed effects on treatment adherence emerged at 6- and 12-month follow-ups. There were no immediate or delayed effects on adolescents' adjustment to diabetes or diabetic control.

CONCLUSIONS — BFST yielded lasting improvement in parent-adolescent relationships and delayed improvement in treatment adherence, but it had no effect on adjustment to diabetes or diabetic control. A variety of adaptations to BFST could enhance its impact on diabetes outcomes.

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T reatment of type 1 diabetes is directed at maintaining near-normal blood glucose levels (1) with a regimen including several daily insulin injections or the use of an insulin pump, self-monitoring blood glucose, a prescribed meal plan, regular exercise, and problem-solving tactics to regulate blood glucose. Family conflict has been associated with poor treatment adherence and poor metabolic control among youths with type 1 diabetes in many cross-sectional studies (2) and in a few longitudinal investiga-

tions (3–6). Other research has implicated parent-adolescent conflict specifically as a correlate of poor treatment adherence (7), inadequate diabetic control (7,8), and poor psychological adjustment to diabetes (9). Therefore, it is reasonable to hypothesize that an intervention that enhances family communication and conflict resolution would improve adaptation to diabetes, treatment adherence, and diabetic control. Previous studies supporting the effectiveness of family therapy with this population and targeting treat-

ment adherence (10), diabetic control (10,11), and adjustment to diabetes (11) were not well-controlled trials of interventions targeting family problem-solving and communication.

We have evaluated the application of Robin and Foster's (12) integration of Behavioral–Family Systems Therapy (BFST) for families of adolescents with diabetes. We previously reported that BFST yielded short-term improvement in parent-adolescent relations and conflict resolution (13) and improvement in directly observed family communication that continued for 12 months (14). Families also rated BFST as more acceptable, applicable, and effective than a multifamily educational support group (15). Despite these benefits, BFST had little or no effect on treatment adherence, adolescents' psychological adjustment to diabetes, or metabolic control. It is possible that the intervention might have had delayed effects on these outcomes. In addition, maintenance of the obtained treatment effects alone is of interest. Therefore, the present study reports the effects of BFST at 6 and 12 months of follow-up on measures of parent-adolescent relationships and adolescents' psychological adjustment to diabetes, adherence to the diabetes regimen, and diabetic control.

RESEARCH DESIGN AND METHODS — This trial has been previously described in detail, including the precise methodology (13–16).

Participants
Type 1 diabetic adolescents and their parents were recruited in St. Louis, MO, and Jacksonville, FL. Recruitment included an initial confirmation of eligibility based on demographic factors, followed by a screening process to ensure that enrolled families had at least moderate levels of parent-adolescent conflict. Initially, 380 families were informed of the study. Adolescents eligible for the study met the following criteria: aged 12–17 years; having type 1 diabetes ≥1 year; no other major chronic diseases; no mental retar-

dation; not incarcerated, in foster care, or in residential psychiatric treatment; and no diagnoses of psychosis, major depression, or substance abuse disorder in adolescents or parents during the previous 6 months. Each parent or stepparent residing with the patient was required to participate in the study, and other adult caregivers were allowed to participate.

Then, interested families who met the above criteria ($n = 178$) gave their written informed consent and completed two screening questionnaires: the Conflict Behavior Questionnaire (CBQ) (17) and the Diabetes Responsibility and Conflict (DRC) scale (18). Specified cutoff scores were expected to exclude ~60% of families (CBQ $\geq$ 5 and DRC $\geq$ 24). Only families in which at least one member obtained a score exceeding one of these cutoffs were eligible. Of 132 families scoring above this criterion, 119 (90%) enrolled in the study. Participants included 119 adolescents, 117 female caregivers, and 82 male caregivers.

Measures

Various questionnaires and biochemical data were obtained at baseline evaluation and at follow-up evaluations scheduled at posttreatment (3 months) and again at 6 and 12 months after treatment ended. The questionnaires sought the respondents' ratings of specific behavioral variables over the preceding 3-month period to ensure temporal congruity among the various measures. A detailed manual ensured the equivalence of the procedures at the two sites.

Demographic factors. Parents reported the basic demographic information and the data needed for estimating socioeconomic status with the Hollingshead Four Factor Index of Social Status (A.B. Hollingshead, unpublished data).

General parent-adolescent relationships. The Parent-Adolescent Relationship Questionnaire (PARQ) was developed by Robin et al. (19) to assess the primary constructs in the behavioral–family systems model of parent-adolescent conflict. It yields three-factor-analytically derived scales: Overt Conflict/Skill Deficits, Extreme Beliefs, and Family Structure. There are separate forms for adolescents (314 true/false items) and parents (280 items), and normative data were available from 314 adolescents and 427 parents. During each administration of this instrument, participants were instructed to rate

family behavior over the preceding 3 months. Internal consistency (Cronbach's α coefficient), calculated on data obtained from this sample, ranged from 0.73 to 0.89 for the three scales and did not differ among mothers, fathers, and adolescents.

Type 1 diabetes–specific psychological adjustment. The Teen Adjustment to Diabetes Scale (TADS) is a 21-item Likert-type scale with parallel parent and adolescent forms that measures adolescent behavioral, affective, and attitudinal adjustment to diabetes over a 3-month period (9). Higher scores indicate more favorable adjustment. Internal consistency, calculated from data obtained from a total of 604 participants in the present and previous studies, was 0.88 for adolescents, 0.91 for mothers, and 0.84 for fathers.

The DRC assesses parent-child division of diabetes responsibilities and family conflict over 15 diabetes tasks during the preceding 3 months (18). Only the conflict items were used in this study because family division of diabetes responsibilities was not targeted by BFST in this study. Internal consistency based on the present sample was 0.92 for adolescents, 0.86 for mothers, and 0.89 for fathers.

Type 1 diabetes treatment adherence. The 14-item Self-Care Inventory (SCI), which was validated by Greco et al. (20), was used to measure diabetes treatment adherence during the preceding 3 months. The SCI correlates significantly with corresponding parts of Johnson's (21) recall interview method and with GHb level. Higher scores indicate better treatment adherence. Total scores on the parent and adolescent forms of the SCI were used for this report. Internal consistency based on this sample was 0.76 for adolescents, 0.81 for mothers, and 0.82 for fathers.

Health status. Using affinity chromatography methods, laboratory staff collected a 3-cm^3 venous blood sample from each patient for total GHb assays to index recent glycemic control. The normal range for the assay was ~6–8%, and within the range typical of adolescents with diabetes, it yields results that are 2–3% higher than the HbA_{1c} assay, which has been widely adopted since this study was initiated.

Procedure

At the end of the baseline evaluation, a research assistant randomly assigned each

family to one of the three conditions described below. Randomization was stratified by the adolescent's sex and by the treatment center, so that each center enrolled a similar number of boys and girls into the three groups.

Current therapy. Patients in the current therapy (CT) group (as well as those in the other groups) received standard diabetes therapy from pediatric endocrinologists, including an examination by a physician and a GHb assay at least quarterly; two or more daily injections of mixed intermediate- and short-acting insulins; self-monitoring of blood glucose and recording of test results; diabetes self-management training; a prescribed diet; physical exercise; and an annual evaluation for diabetic complications.

Education and support. In the first 3 months of the study, families in the education and support (ES) group attended 10 group meetings that provided diabetes education and social support. This was formulated as a common mental health service for families of this population and as a "best alternative therapy" comparison. A social worker at one center and a health educator at another center served as group facilitators. Panels of two to five families began and completed 10 sessions together; the parents and the adolescent with diabetes attended the sessions. The same educational materials and session outlines were used at both sites, and the two facilitators conferred weekly by telephone to ensure cross-site consistency of the intervention. Family communication and conflict resolution skills were specifically excluded from session content, because these are the primary targets of BFST. Each session included a 45-min educational presentation by a diabetes professional, followed by a 45-min interaction among the families about a topic led by the facilitator.

BFST. Adolescents and caregivers in this group received 10 sessions of BFST (12). Sessions were conducted by one woman and one man (P.G., M.A.H.) who received extensive training in this approach. A detailed therapy manual supplemented the guidelines presented by Robin and Foster (12) and included session outlines, handouts, and homework assignments that were used at both sites. BFST consisted of four therapy components that were used in accordance with each family's treatment needs as identified by the project psychologists and was based on study

data and family interaction during sessions.

Problem-solving training. Problem-solving training provided families with a behavioral contracting approach to conflict resolution with training in problem definition; generation of alternative solutions; group decision-making, planning, implementation, and monitoring of the selected solution; and renegotiation or refinement of the ineffective solutions.

Communication skills training. Communication skills training included instructions, feedback, modeling, and rehearsal targeting common parent-adolescent communication problems.

Cognitive restructuring. Cognitive restructuring methods were used to identify and change family members' irrational beliefs, attitudes, and attributions that may have impeded effective parent-adolescent communication and conflict resolution.

Functional and structural family therapy. Functional and structural family therapy interventions targeted anomalous family systemic characteristics (e.g., weak parental coalitions or cross-generational coalitions) that may have impeded effective problem solving and communication.

Families received an individualized treatment plan guided by baseline assessments and ongoing observation of family interactions. Sessions consisted of family problem-solving discussions focusing on diabetes-related or general conflicts as appropriate for each family. The psychologists used standard behavior therapy techniques of instruction, feedback, modeling, and rehearsal. Behavioral homework (i.e., encouraging families to practice targeted skills at home) was assigned at each session and reviewed at the next session.

Participation incentives and intervention adherence

To maximize completion of data collection, families were paid $100 ($50 each for the parents and adolescent) on completion of each evaluation. ES and BFST families could earn another $100 if they completed all 10 scheduled intervention sessions. The posttreatment evaluations were completed by 115 families (96%), the 6-month follow-up by 113 families (95%), and the 12-month follow-up by 108 families (91%). All scheduled intervention sessions were completed by 87% of BFST families and 91% of ES families.

Psychological services outside of the study were received by 5 CT families (22 sessions total), 3 ES families (21 sessions total), and no BFST families. There were no psychiatric hospitalizations.

Data reduction

To reduce the number of statistical comparisons and enhance the reliability of outcome measures, family composite scores were calculated by summing and averaging the scores of individual family members. In each case, there were significant positive correlations (range 0.45–0.83) between family members' scores. This procedure reduced the number of statistical comparisons and reduced variability in some measures.

RESULTS

Sampling and randomization

The 119 adolescents and their families who participated had the following characteristics (mean ± SD): age 14.3 ± 1.3 years, duration of diabetes 5.2 ± 3.7 years, Hollingshead Four Factor Index of Social Status raw score 43.1 ± 12.0, and total GHb 11.9 ± 3.1%. Sex distribution was 51 males and 68 females. Racial composition (i.e., distributions that typify the clinic populations at the two centers) was 79% Caucasian, 20% African-American, and 1% Hispanic. Analysis of Tanner stage revealed 2.5% stage I, 51.3% stages II–IV, and 46.2% stage V. Family composition was 54.6% living with both biological parents, 32% with one biological parent, 11.8% with one biological and one stepparent, and 1.6% with other.

Despite careful randomization, the three treatment groups differed demographically at baseline. The BFST group included significantly fewer intact families and more single-parent families than did the other two groups. The divorce rate for the CT group was significantly lower than that for the ES and BFST groups. Based on previous related studies, these demographic differences could manifest in between-group differences in the primary study outcomes.

In fact, there were baseline differences in several outcome measures, indicating greater conflict and poorer adaptation to diabetes among BFST families. Analyses of variance with the treatment group as the between-subject factor were conducted for family composite baseline scores on the outcome measures.

A significant main effect for groups, indicative of less favorable status for the BFST group, was obtained on PARQ Overt Conflict/Skill Deficits scale, DRC, TADS, and SCI. Subsequent analyses compensated for these pretreatment group differences.

Statistical analysis strategy

Inequality of the groups on the dependent measures at baseline creates interpretive difficulties for most analytic methods, because it impedes differentiation of true treatment effects from nonspecific changes due to regression toward the mean (22). To compensate for this complication, primary statistical analyses consisted of repeated-measures analyses of covariance (RM-ANCOVA), treating the baseline values of the respective outcome measures as the covariates. Post hoc analyses were then performed using the Tukey Honestly Significant Differences test. Table 1 reports the baseline values for the outcome measures along with change scores relative to baseline for each group at posttreatment and at 6- and 12-month follow-up. Considering the number of families who completed the entire study, there was sufficient statistical power (≥0.80) at each follow-up to detect a difference between groups of 0.9% in HbA_{1c} level, which was the primary outcome measure.

Because previous analyses had revealed immediate posttreatment effects on TADS, SCI, and GHb that were dependent on the adolescents' age and sex, these variables were treated as additional between-subject factors for analyses of these particular dependent variables. Two age-groups were formed based on a median split for age at 14.3 years.

Measures of general parent-adolescent relationships

As seen in Table 1, the BFST group demonstrated lasting improvement on the PARQ Extreme Beliefs scale [$F(2,104) = 4.56, P < 0.013$], with change scores that differed significantly ($P < 0.05$) from both the CT and ES groups at all three evaluations. On the PARQ Overt Conflict/Skill Deficits scale, a significant between-group effect was found [$F(2,104) = 3.39, P < 0.04$] and post hoc analyses showed that at posttreatment and 6-month follow-up, BFST scores differed significantly from those of the CT group ($P < 0.03$ at posttreatment and $P < 0.05$ at 6 months), but not from those of the ES group. These

Table 1—Baseline family composite questionnaire scores and GHb results for each group and changes in these measures relative to baseline at posttreatment and 6- and 12-month follow-up evaluations

	Baseline			Posttreatment			6-month follow-up			12-month follow-up		
	CT	ES	BFST	CT	ES	BFST	CT	ES	BFST	CT	ES	BFST
n	41	40	38	40	38	37	40	37	36	38	36	34
PARQ Overt Conflict/ Skill Deficits	51.2 ± 3.9	52.8 ± 5.4	53.3 ± 5.7	–0.2*	–1.4*	–3.1†	–0.8*	–1.4*†	–2.4†	–2.5*	–2.8*	–3.0*
PARQ Extreme Beliefs	49.6 ± 3.4	51.2 ± 5.1	51.1 ± 4.4	–0.3*	–0.9*	–4.1†	–1.2*	–0.8*	–3.9†	–0.9*	–1.9*	–4.2†
PARQ Family Structure	51.7 ± 6.6	52.3 ± 6.4	51.7 ± 5.6	–0.7*	–1.1*	–2.0*	–1.1*	–2.1*	–2.6*	–2.8*	–3.2*	–2.4*
DRC	28.6 ± 8.3	29.5 ± 8.1	32.5 ± 9.4	–2.9*	–3.1*	–6.8†	–2.6*	–4.6†	–7.0‡	–3.8*	–4.9*†	–6.1†
SCI	51.1 ± 6.6	49.4 ± 7.7	46.7 ± 9.3	–1.4*	0.1*	0.8*	–2.6*	–0.3*†	1.8†	–5.4*	–1.2†	3.3‡
TADS	78.2 ± 10.5	77.0 ± 10.2	72.8 ± 9.7	–0.8*	0.0*	0.7*	–2.3*	–1.9*	–2.9*	–4.6*	–2.2†	–1.9†
GHb (%)	11.8 ± 3.1	11.8 ± 2.9	11.9 ± 3.3	–0.1*	–0.2*	0.4*	0.6*	0.5*	0.2*	1.1*	0.3*	0.9*

Data are means ± SD, unless otherwise indicated. Higher scores are favorable for SCI and TADS and unfavorable for other measures. Within the three columns for each follow-up evaluation, values with different superscripts differ significantly at $P < 0.05$, based on post hoc analyses.

differences dissipated at 12-month follow-up. For the PARQ Family Structure scale, there was a significant effect for time; the scores for all three groups declined over time, and there were no between-group differences at any measurement point.

Diabetes-specific psychological adjustment
Table 1 also summarizes scores obtained for the three groups on two measures of adolescents' diabetes-specific psychological adjustment. For the DRC, a statistically significant main effect for groups was obtained [F (2,103) = 4.08, $P < 0.03$]. At the posttreatment and at the 6-month follow-up, BFST differed significantly from those in the CT group ($P < 0.04$) and those in the ES group ($P < 0.05$). At 12 months, BFST differed among those in the CT group ($P < 0.05$), but not from those in the ES group. No significant between-group or interaction effects were obtained for the TADS at any measurement point.

Treatment adherence
Analyses of change in SCI scores revealed a significant group by time interaction effect [F (2,104) = 3.80, $P < 0.05$] such that there were no significant between-group differences at posttreatment, but the BFST group showed improved treatment adherence at 6- and 12-month follow-up, whereas the CT and ES groups showed deteriorated adherence. Post hoc analyses confirmed significant differences between the BFST group and both of the other groups at 6- and 12-month follow-up ($P < 0.05$). There were no sig-

nificant interaction effects between the treatment condition and either age or sex.

Health status measures
Total GHb values increased throughout the study, as documented by a significant main effect for time [F (1,102) = 3.98, $P < 0.05$], but there were no significant between-group or interaction effects on GHb at any measurement point. There were five hospitalizations and nine emergency department admissions during the study, with no between-group differences in these events at any measurement point.

CONCLUSIONS — This study compares the long-term effects of BFST with current medical therapy or with participation in a diabetes support group. The goals of the study went beyond those of conventional treatment outcome studies in clinical psychology by seeking to show that change in a clinically relevant process (parent-adolescent relationship) yielded durable changes in disease-related functioning and health status.

Despite careful randomization, the three groups differed at baseline on several demographic and psychological dimensions, possibly impeding the capacity of the study to yield clear treatment effects. RM-ANCOVA, treating the baseline values of the outcome measures as covariates, enabled some degree of statistical control over these pretreatment differences.

We previously reported that BFST yielded short-term improvements in self-report and direct observation measures of parent-adolescent communication and family relationships, but that benefits in

terms of diabetic control, treatment adherence, and diabetes-specific psychological adjustment depended on the age and sex of the adolescent (13,14). We also previously reported that at posttreatment, boys and younger girls showed modest improvement on measures of diabetic control and psychological adjustment to diabetes, whereas older girls showed deterioration on these measures. We have also published social validity data indicating that families rated BFST as more acceptable, applicable, and effective than ES as a treatment for family conflict and communication problems commonly encountered by these families (15).

The present results indicate that treatment effects on certain measures were durable, with persistence of significant between-group differences favoring BFST at either the 6- or 12-month follow-up for the PARQ Extreme Beliefs, the PARQ Overt Conflict/Skill Deficits, and the DRC scales. A delayed treatment effect was evident at 6- and 12-month follow-up on treatment adherence, as measured by the SCI. In a previous study (15), we reported no between-group differences in either TADS scores or GHb values, and no delayed treatment effects on either of these measures emerged from the present analyses. In addition, none of the immediate posttreatment interactive effects that were dependent on the adolescent's age and sex (e.g., GHb and TADS) persisted at long-term follow-up. The delayed therapeutic effect of BFST on treatment adherence (SCI scores) may indicate that achievement of beneficial impact of the treatment on diabetes-specific outcomes requires prolonged change in family interaction

patterns. We could speculate further that the absence of delayed effects on psychological adjustment to diabetes (TADS) and diabetic control (GHb) may indicate that change in these outcomes may require even more robust and lasting change in family behavior following intervention.

Given the analytic problems inherent in evaluation of change scores when groups differ at baseline, the results of the RM-ANCOVA should be interpreted cautiously. Treatment of baseline outcome measures as covariates enabled some degree of statistical control over these complications, but it is possible that the groups differed qualitatively, despite this statistical adjustment. The failure of the randomization scheme in the present study illustrates the importance of stratification based on key outcomes to increase the probability of pretreatment equivalence of the groups.

Retention of 91% of the sample over the 15-month study was accomplished with the use of financial incentives for the participants. The present study was conceived as an investigation of the efficacy of BFST under ideal conditions. Further research will be necessary to determine whether BFST is effective in typical clinical settings in which such incentives are not feasible.

The present study expands the psychological treatment-outcome literature pertinent to adolescents with type 1 diabetes. Previous studies supporting the efficacy of family therapy for this population (10,11) lacked the large sample size, appropriate control conditions, and multivariate assessment methods employed in the present study. The Diabetes Control and Complications Trial (DCCT) (1) showed that prolonged maintenance of near-normoglycemia reduces the occurrence of diabetic complications by 50–75%. These striking results were achieved with intensified application of available therapy, suggesting that translation of the DCCT findings into clinical practice depends on the validation of effective interventions for promoting family adaptation to this more demanding regimen. In contrast to the adolescents recruited for the DCCT, the sample recruited for the present study consisted of patients who were in chronically poor diabetic control and whose families had been unable to incorporate adequate diabetes self-management habits into their daily rou-

tines. Further refinements to the BFST could enhance its impact on diabetes outcomes with this challenging population. Other studies that have demonstrated a greater impact of behavioral interventions on diabetes outcomes have incorporated elements of intensive diabetes management (23) and training in diabetes problem solving (24,25) in their interventions.

Although the present study demonstrates some promise for BFST, the results suggest avenues for further research directed at increasing the impact of this technique on type 1 diabetes–specific outcomes. These avenues could include *1*) targeting families of younger adolescents with BFST (24,26); *2*) ensuring that BFST targets identification and reduction of each family's unique barriers to treatment adherence and diabetic control (27); or *3*) integrating BFST with other effective intervention strategies, such as multifamily support groups (25,28), training for the use of blood glucose data for diabetes problem solving (24,25), achieving an appropriate balance of parent and adolescent responsibility for diabetes management (26), employing a longer duration of intervention (24), and implementing regularly occurring "booster" sessions (29). The present findings suggest that further research on BFST can yield a practical intervention that can improve adaptation to diabetes among adolescents and their families.

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