Randomized Trial of Behavioral Family Systems Therapy for Diabetes

Maintenance of effects on diabetes outcomes in adolescents

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OBJECTIVE — Studies showing that family communication and conflict resolution are critical to effective management of type 1 diabetes in adolescents have stimulated interest in evaluating psychological treatments targeting these processes. Previous trials have shown that Behavioral Family Systems Therapy (BFST) improved parent-adolescent relationships but not treatment adherence or glycemic control. This study evaluates a revised intervention, BFST for Diabetes (BFST-D), modified to achieve greater impact on diabetes-related family conflict, treatment adherence, and metabolic control.

RESEARCH DESIGN AND METHODS — A sample of 104 families of adolescents with inadequate control of type 1 diabetes was randomized to either remain in standard care (SC) or to augmentation of that regimen by 12 sessions of either a multifamily educational support (ES) group or 12 sessions of BFST-D over 6 months. Pertinent measures were collected at baseline and at follow-up evaluations at 6, 12, and 18 months.

RESULTS — BFST-D was significantly superior to both SC and ES in effects on A1C, while effects on treatment adherence and family conflict were equivocal. Improvement in A1C appeared to be mediated by improvement in treatment adherence. A significantly higher percentage of BFST-D youth achieved moderate or greater improvement (>0.5 SD) in treatment adherence compared with the SC group at each follow-up and the ES group at 6 and 18 months. Change in treatment adherence correlated significantly with change in A1C at each follow-up.

CONCLUSIONS — These results support the efficacy of BFST-D in improving A1C, but further research is needed to identify the mechanisms of this effect and to achieve cost-effective dissemination of the intervention.

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Numerous cross-sectional (1–5) and longitudinal studies (6–8) have implicated family communication, conflict resolution, and problem-solving skills as critical elements of effective family management of type 1 diabetes during adolescence. Hence, psychological and behavioral interventions targeting these mechanisms could yield beneficial effects on diabetes outcomes.

We previously reported (9–12) that Behavioral Family Systems Therapy (BFST) yielded durable improvements in self-reported and directly observed parent-adolescent interactions in families of youth with poorly controlled type 1 diabetes compared with the effects of a multifamily educational support (ES) group or standard care (SC). BFST yielded significant effects on both questionnaire (11) and direct observation measures (10) of family communication; on youth and maternal ratings of the effectiveness, applicability, and acceptance of the intervention (9); and, transiently, on self-reported treatment adherence (12). However, the BFST intervention did not yield corresponding improvements in metabolic control or lasting improvements in treatment adherence (9–12). Therefore, we revised the BFST intervention in an effort to enhance its impact on these diabetes outcomes (13). The revisions included required targeting of diabetes-specific behavioral problems, extension of treatment from 3 to 6 months, training in behavioral contracting techniques for all families, a 1-week parental simulation of living with type 1 diabetes, and optional extension of therapeutic activities to other extrafamilial social environments affecting the child's diabetes management (13). We have reported elsewhere (13) that 6 months of exposure to this revised intervention, which we have termed Behavioral Family Systems Therapy for Diabetes (BFST-D), yielded immediate posttreatment gains in glycemic control, treatment adherence, and family communication in families of adolescents with suboptimal diabetes management when compared with a multifamily ES group or standard medical care. The present study evaluates the maintenance of these improvements over an additional 12 months' follow-up of these families.

RESEARCH DESIGN AND METHODS

— Detailed descriptions of the study sample and procedures have been previously published (13), so limited details are provided here. The present study focuses on the most important targets of the BFST-D intervention: A1C, treatment adherence, and diabetes-related family conflict that were of primary interest to readers of this journal. Space limitations prevent inclusion of analyses of potential moderators of inter-

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Abbreviations: BFST, Behavioral Family Systems Therapy; BFST-D, Behavioral Family Systems Therapy for Diabetes; DRC, Diabetes Responsibility and Conflict; DSMP, Diabetes Self-Management Profile; ES, educational support; SC, standard care.

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

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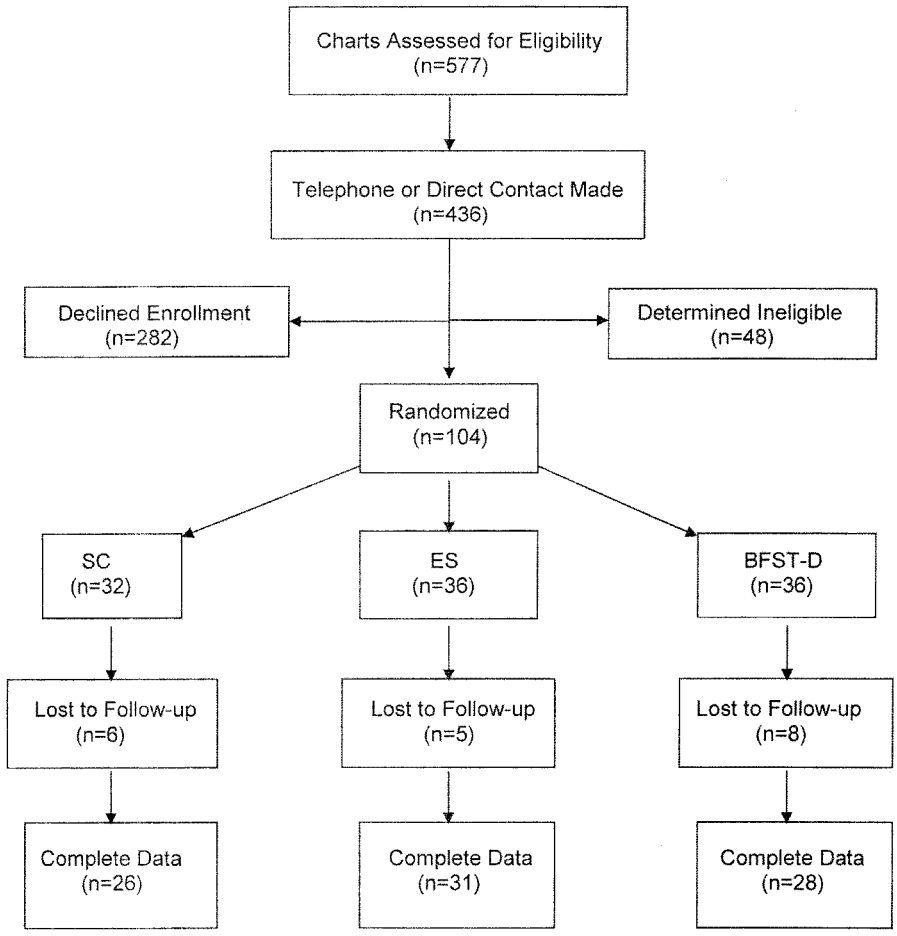

Figure 1—*Summary of recruitment, randomization, and participants' progress through the trial.*

vention outcomes that were also measured. Figure 1 summarizes participants' progress through the trial from the perspective of the CONSORT (Consolidated Standards of Reporting Trials) criteria (14) for randomized trials.

Families of 104 adolescents with recent A1C >8.0% were recruited from two pediatric diabetes referral centers. While the initial sampling plan targeted enrollment of 120 families, we were unable to reach that goal because of funding constraints. Additional enrollment criteria—such as absence of severe psychopathology or substance abuse, functional literacy in English, geographic stability, and established care for type 1 diabetes at the enrolling center—ensured that the enrolled patients and families were appropriate candidates for the interventions being compared in this study. Table 1 summarizes the demographic characteristics of the sample; there were no statistically significant differences among the three groups on any of these demographic variables at baseline. Youth with parent-reported racial or ethnic minority status constituted 37% of the sample, and 53% were female.

A randomized between-group experimental design was employed, with repeated measures at baseline and at the end of treatment (6 months) and at 12- and 18-month follow-up evaluations. Of the 104 families who enrolled, 92 (88%) completed the 6-month evaluation, 88 (85%) completed the 12-month evaluation, and 85 (82%) completed the 18-month evaluation. Compared with the retained sample who completed all evaluations, those who did not complete the study were of significantly lower socioeconomic status and significantly less likely to be living with both biological parents. There were no other significant differences between completers and noncompleters. After the baseline evaluation described below, families were randomized to 6 months of treatment consisting of SC for type 1 diabetes alone or augmented by either 12 sessions of a multifamily ES group or 12 sessions of the BFST-D intervention. Thereafter, all patients reverted to the SC medical regimen. Follow-up evaluations occurred at the end of the treatment phase of the study and at 12 and 18 months after the baseline evaluation, corresponding to 6 and 12 months after completion of the intervention period. A comparison group consisting of the earlier version of BFST was

Table 1—*Characteristics of the three groups of study subjects at baseline*

	SC	ES	BFST-D
Age (years)	14.2 ± 1.9	14.4 ± 1.9	13.9 ± 1.9
Diabetes duration (years)	5.9 ± 4.0	5.5 ± 3.2	5.1 ± 3.0
A1C (%)	9.5 ± 1.5	9.7 ± 1.6	9.6 ± 1.6
Hollingshead socioeconomic status index	40.3 ± 14.2	40.1 ± 11.6	40.4 ± 13.7
Sex			
Male	16 (50)	20 (56)	21 (58)
Female	16 (50)	16 (44)	15 (42)
Race/ethnicity			
Caucasian	17 (53)	27 (75)	22 (61)
African American	11 (34)	9 (25)	12 (33)
Hispanic	2 (6)	0	1 (3)
Other	2 (6)	0	1 (3)
Family composition			
Intact	13 (41)	15 (42)	16 (43)
Blended	4 (13)	5 (14)	7 (19)
Single parent	11 (34)	12 (33)	11 (32)
Other	4 (13)	4 (11)	2 (5)
Insulin modality			
Injections	25 (78)	27 (75)	27 (75)
Insulin pump	7 (22)	9 (25)	9 (25)

Data are means ± 1 SD or *n* (%).

Table 2—*Outcome measures at each measurement point for the three groups*

Group	Baseline	3 months	6 months	9 months	12 months	15 months	18 months
DSMP total score							
SC	53.0 ± 10.8	—	52.1 ± 8.8	—	51.6 ± 11.0	—	53.3 ± 10.9
ES	55.1 ± 9.5	—	54.7 ± 10.3	—	55.6 ± 11.7	—	55.3 ± 11.2
BFST-D	55.4 ± 10.8	—	57.1 ± 7.6	—	58.2 ± 9.1	—	57.3 ± 10.4
DRC scale family composite score							
SC	25.7 ± 6.8	—	29.2 ± 10.2	—	25.0 ± 11.1	—	23.6 ± 10.1
ES	29.1 ± 6.8	—	31.7 ± 11.4	—	27.7 ± 8.9	—	28.8 ± 9.8
BFST-D	27.2 ± 7.6	—	26.3 ± 8.8	—	25.7 ± 11.0	—	25.4 ± 10.4
A1C (%)							
SC	9.6 ± 1.5	9.2 ± 1.7	9.1 ± 1.8	9.5 ± 1.7	9.6 ± 1.6	9.6 ± 1.6	9.6 ± 1.7
ES	9.7 ± 1.6	8.8 ± 1.5	8.9 ± 1.2	9.5 ± 1.3	9.3 ± 1.4	9.6 ± 1.4	9.5 ± 1.5
BFST-D	9.6 ± 1.6	8.9 ± 1.6	8.8 ± 1.5	8.7 ± 1.3	8.9 ± 1.4	8.6 ± 1.3	8.8 ± 1.5

Data are means ± SD.

considered but not pursued because of fiscal and sample size considerations.

Measures

The following measures were collected during the four evaluations.

General information form. Patients provided demographic and medical information and data needed for calculating the Hollingshead Index of Social Status (A.B. Hollinghead, unpublished observations).

A1C. Using the DCA-2000+ device, we measured A1C at each quarterly diabetes clinic visit. Previous studies have demonstrated a high correlation between DCA-2000 and reference laboratory results for this assay (15), as well as between DCA-2000 results obtained at the two different sites.

Diabetes Self-Management Profile. Trained interviewers conducted the Diabetes Self-Management Profile (DSMP), a 24-item structured interview that yields an estimate of overall treatment adherence over 3 months. Interviewers were not otherwise associated with the diabetes team. Parents and youth were interviewed separately, and their scores were averaged to yield a single estimate of treatment adherence. Reliability and validity of the DSMP have been shown in several studies (16–23).

The Diabetes Responsibility and Conflict scale. The Diabetes Responsibility and Conflict (DRC) scale is a 15-item Likert scale measure that yields an estimate of diabetes-specific family conflict (24). Parent and youth scores were combined to yield a single estimate of family conflict about diabetes. For this sample, α coefficient was 0.91 for parents and 0.87 for youth.

Hypotheses and statistical analyses

The central hypotheses of the study were that BFST-D would yield significantly more improvement in glycemic control (measured by A1C), diabetes-related family conflict (measured by the DRC scale), and diabetes treatment adherence (measured by the DSMP) than the SC and ES groups at each follow-up evaluation. Repeated-measures ANOVA with the SPSS generalized linear models approach (25) was used. Missing data were replaced by moving the preceding value forward. Significant between-group or group-by-time interaction effects were followed by planned comparisons using independent-samples Student's *t* tests to isolate the sources of the significant effects.

To further explore whether changes in treatment adherence mediated treatment effects of BFST-D on A1C, several additional analyses were completed. First, we calculated the proportion of youth in each group who realized at least moderate treatment effects (0.5 SD or five points) on total scores for treatment adherence (measured by the DSMP) at 6 months. Next, we calculated Pearson correlations between changes in DSMP scores and changes in A1C at each follow-up.

RESULTS

— Table 2 summarizes the effects of BFST-D at each follow-up relative to those of the SC and ES conditions on A1C, DRC scale, and DSMP scores, respectively (means ± 1 SD). There were no significant between-group differences at baseline on any of these three outcome measures. As portrayed in Table 2, A1C levels for all three groups appeared to decline during the first 6 months of the study, but the levels then reverted toward baseline values in the SC and ES groups, while remaining below baseline and also lower than both ES and SC groups from 6 to 18 months in the BFST-D group. This observation was confirmed by repeated-measures ANOVA, which revealed a statistically significant group-by-time interaction effect with $F(12,600) = 4.29$, $P < 0.001$. Subsequent post hoc tests confirmed that mean A1C for the BFST-D group was significantly lower ($P < 0.05$) than that of the SC group at months 6, 9, 12, 15, and 18 and significantly lower than that of the ES group at months 9, 15, and 18.

Table 2 also shows mean family composite DRC-scale scores at each measurement point for each group. The data appear to confirm consistent reduction in conflict favoring BFST-D over SC and ES. Repeated-measures ANOVA yielded a significant main effect for groups [$F(2,82) = 3.27$, $P < 0.03$], but the group-by-time interaction effect was not significant. Post hoc analyses showed that diabetes-related family conflict for the BFST-D group was significantly lower than those of both SC and ES groups only at 6 months, but not thereafter.

Finally, Table 2 presents mean family composite DSMP scores at each measurement point for each group. Repeated-measures ANOVA yielded a significant main effect for groups [$F(2,81) = 3.62$, $P < 0.03$], but, again, the group-by-time interaction effect was not significant. Post hoc comparisons confirmed that the BFST-D group had significantly better treatment adherence than the SC group at each follow-up evaluation, but there were no significant differences between the

Table 3—*Percentage of youth in each group who achieved improvement in DSMP total score of 5 or more points (>0.5 SD) at each follow-up relative to baseline scores*

Group	6 months	12 months	18 months
SC	31.1	21.4	17.8
ES	28.4	32.1	28.4
BFST-D	46.4	35.7	34.4

Scores for the BFST-D group were significantly superior to those of the SC group ($P < 0.05$) at all three follow-ups and the ES group only at 6 months.

BFST-D and ES groups or between the ES and SC groups at any measurement point.

Table 3 presents the percentage of youth in each treatment group who achieved increases in DSMP scores over baseline of five points or more (>0.5 SD) at the 6-, 12-, and 18-month follow-ups. Tests of the significance of a difference in proportions (24) showed that the percentage of BFST-D youth meeting this criterion was significantly higher than that of the SC group at all follow-ups and significantly higher than that of the ES group at the 6- and 18-month follow-ups.

Pearson correlations between change in A1C and change in DSMP scores were calculated at each follow-up point. These correlations were −0.23 at 6 months ($P < 0.04$), −0.31 at 12 months ($P < 0.01$), and −0.26 at 18 months ($P < 0.03$).

CONCLUSIONS — The results of this randomized controlled trial generally support the hypothesized effectiveness of the revised BFST-D intervention in reducing A1C in adolescents with suboptimal glycemic control. The findings suggest that adaptations made to the earlier BFST intervention enhanced the impact of the intervention on this key diabetes outcome. Improvement in A1C was confirmed by a significant group-by-time interaction effect and by subsequent post hoc analyses showing that the BFST-D group had sustained improvement in glycemic control over time while the means of the SC and ES groups returned to baseline levels after a slight initial decline. A plausible interpretation of these findings is that the initial improvement in A1C realized by the SC and ES groups represented a nonspecific effect of study participation that was not durable, while BFST-D families were able to sustain this improvement.

With respect to family conflict related to type 1 diabetes (DRC scale family composite scores), the absence of a significant group-by-time interaction effect implies that BFST-D did not selectively improve this outcome measure. However, there was not a significant difference in DRC scale scores between groups at baseline, but at 6 months the BFST-D group had significantly lower DRC scale scores than both ES and SC families. No significant difference was found at the 12-month and 18-month follow-ups. From these results it is difficult to determine the importance of reduced family conflict in the sustained improvement in A1C.

Somewhat mixed findings were also obtained with respect to changes in treatment adherence (DSMP family composite scores), since the group-by-time interaction was again nonsignificant. There were no significant differences among groups at baseline, but, thereafter, the BFST-D group had significantly higher DSMP scores than the SC group at each follow-up evaluation. There were no statistically significant differences between the BFST-D and ES groups in DSMP scores at any measurement point. Since one would expect improved adherence to enhance glycemic control, additional analyses were performed to evaluate the extent to which reduction in A1C was mediated by improvements in treatment adherence. Youth in the BFST-D group were significantly more likely than those in either the SC or ES groups to demonstrate moderate or greater improvement in treatment adherence (>0.5 SD) at 6 months, and this effect persisted compared with the SC group at 12 and 18 months. Correlational analyses showed that, relative to baseline scores, improvement in treatment adherence was correlated significantly with improvement in A1C at each follow-up. Together, these two analyses support the argument that glycemic benefits of BFST-D were mediated to some extent by improved treatment adherence.

BFST-D consistently proved superior to SC relative to effects on the diabetes outcomes, while ES also appeared to exert some beneficial therapeutic effects. This observation suggests that delivery of all or part of the BFST-D components in a multifamily group context might capitalize on the benefits of ES and magnify the gains achieved through BFST-D. Such an adaptation could reduce the cost of delivering BFST-D and perhaps make it more broadly accessible. Demonstration of effectiveness of BFST-D in a group or multifamily setting would require further study.

It is somewhat perplexing that treatment effects on A1C were more robust than those on the self-reported measures of family conflict and treatment adherence, since change in these latter two mechanisms was presumed to be prerequisite to improvements in glycemic control. There are several possible explanations for these seemingly inconsistent findings. The weaker effects of BFST-D on the DRC scale and DSMP scores may reflect measurement error inherent in self-report instruments. Correlations between DSMP scores and A1C reported by several different research groups have ranged from −0.22 to −0.60, so it is not surprising that associations between changes in these measures would be modest (17–24). Alternatively, among adolescents with suboptimal family management of type 1 diabetes, improvements in A1C may require only small improvement in adherence and family communication. The DRC scale and DSMP may not be sufficiently sensitive to detect and quantify subtle changes in these dimensions of family management of type 1 diabetes.

As noted in RESULTS, youth from single-parent and low socioeconomic status homes were more likely to withdraw from the study. Since these variables have been associated with poorer adaptation to diabetes, it is possible that the treatment benefits reported in this paper may have been reduced had these participants remained in the study.

We have reported elsewhere (Wysocki T, Harris MA, Buckloh LM, Mertlich D, Lochrie AS, Taylor A, Sadler M, Mauras N, White NH, unpublished observations) that BFST-D yielded durable improvement in directly observed family communication and problem solving skills during this same trial. In that study, quality of parent-adolescent interaction among BFST-D families was rated independently as significantly superior to that of SC in 10 of 12 follow-up comparisons and to that of ES in 6 of 12 follow-up comparisons. Those results also showed significant improvements in the reported individual communication behaviors of mothers and adolescents in the BFST-D group. Changes in family communication behaviors were associated differentially with changes in diabetes outcomes, and the strength of those associations tended to dissipate over time. Taken together, the results obtained during the present randomized controlled trial demonstrate that the revised BFST-D intervention achieved greater impact on A1C than was evident from our initial trial of the BFST interven-

tion. These findings add to a growing list of psychological and behavioral interventions that have some degree of empirical support for improving family management and glycemic control of type 1 diabetes (26–37).

Since treatment effects on the DRC scale and DSMP scores were unclear, the present study yielded equivocal results regarding the specific mechanisms that mediated the obtained improvement in A1C among BFST-D families. Future research should focus on further clarification of this question, and this could be enhanced by studying larger samples of families and through further improvement in the measurement of potential mediators such as treatment adherence and family communication.

The resources required to implement a complex, multicomponent intervention such as that described here are available at few pediatric diabetes centers in the U.S. Even if such resources were broadly available, limitations in third-party coverage could significantly impede access to such services. Thus, adapting BFST-D to make the intervention less labor intensive, and, thus, less expensive, might be valuable. These efforts could include evaluating delivery of BFST-D in multifamily groups; reducing the number of sessions; training other professionals, such as certified diabetes educators, to implement the intervention; or augmenting session content with Internet or automated telephone support systems.

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