

Family Therapy for Adolescents with Poorly Controlled Diabetes: Initial Test of Clinical Significance

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Objective We examined a structured family therapy approach in promoting clinically meaningful improvements in parent–adolescent conflict in adolescents with poorly controlled diabetes. **Method** Eighteen adolescents with poorly controlled diabetes and their parent(s) participated in 10 sessions of home-based Behavioral Family Systems Therapy (BFST). Outcome comparisons were made using a sample of adolescents with poorly controlled diabetes ($n = 40$) from a previous study. Clinically significant improvements were determined by calculating *SD* differences between treatment and comparison groups on measures of diabetes-related and general parent–adolescent conflict. **Results** Home-based BFST produced change in diabetes-related family conflict ranging from 1/3 to 1/2 *SD* and general family conflict ranging from 1/3 to 3/4 *SD*. **Conclusions** BFST produced change in family conflict, a variable shown through previous research to relate to treatment adherence in adolescents with diabetes. The test of clinical significance represents an example of a method useful for pediatric research.

Diabetes mellitus affects up to 1 in 500 children in North America (Chase, 2006). Type 1 diabetes mellitus (T1DM) is thought to be an autoimmune disease in which insulin-producing pancreatic islet cells are attacked and destroyed, the treatment of which is quite complex. Typical regimens include insulin replacement either via multiple injections of insulin per day or an insulin pump, several daily blood glucose checks, regulation of carbohydrates, regular exercise, and management of low blood glucose levels (American Diabetes Association [ADA], 2007). Type 2 diabetes mellitus (T2DM) results from decreased insulin sensitivity and reduced insulin secretion, and is often associated with obesity. Treatment of T2DM in youth generally involves dietary management and regular exercise; however, many youths with T2DM also require insulin injections (ADA, 2007). Thus, the differences in prescribed treatment regimen can be minimal between T1DM and T2DM, particularly for youth with severe or poorly controlled T2DM. Long-term complications for both T1DM and T2DM are the result of elevated blood glucose levels and include blindness, kidney failure, nerve damage and heart, and blood vessel disease (ADA, 2007).

Cross-sectional and prospective studies have demonstrated that higher levels of general and diabetes-related family conflict are related to poorer metabolic control and poorer adherence to treatment in youth with diabetes (Anderson, Miller, Auslander, & Santiago, 1981; Gustafsson, Cederblad, Ludvigsson & Lundin, 1987; Hauser et al., 1990; Miller-Johnson et al., 1994; Wysocki, 1993). As a result, family-based psychosocial interventions targeting family conflict could improve diabetes outcomes. One such intervention, Behavioral Family Systems Therapy (BFST), is a flexible, multi-component intervention targeting family communication and problem solving (Robin & Foster, 1989). Wysocki and his associates demonstrated that 10 sessions of BFST improved family communication and problem-solving based on parent and adolescent report (Wysocki et al., 2000) and direct observation of family interactions (Wysocki et al., 1999). These benefits persisted for 12 months (Wysocki, Greco, Harris, Bubb, & White, 2001). Wysocki and associates (Wysocki et al., 2006, 2007) conducted another randomized trial implementing a modified version of BFST that focused more specifically on diabetes-related

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issues (BFST-D), demonstrating significant improvements in glycemic control, treatment adherence, and diabetes-related family conflict immediately post-treatment, with greater improvements in diabetes-related family conflict and glycemic control for adolescents in very poor glycemic control at baseline. These effects were largely maintained over a 12-month follow-up (Wysocki et al., 2008). Adolescents in these studies all had T1DM.

The studies reviewed above are indicative of the growing empirical support for the efficacy of BFST on psychosocial functioning, family functioning, adherence to treatment, and metabolic control for adolescents with diabetes (Wysocki et al., 2006, 2007, 2008). However, few of these studies have examined whether these observed improvements are clinically, rather than simply statistically, significant (Harris, Greco, Wysocki, & White, 2001). Clinical significance has been defined in several ways; in this context it refers to the extent to which therapeutic interventions used in a clinical trial produce changes in areas targeted by the treatment that are meaningful (Harris et al., 2001). Various methods and criteria have been suggested regarding how to determine clinical significance (Jacobson, Roberts, Berns, & McClinchey, 1999; Jacobson & Truax, 1991), but the common emphasis is that researchers testing clinical interventions should go beyond simply testing statistical significance to include an evaluation of the magnitude or meaningfulness (e.g., whether change results in improved day-to-day functioning; Kazdin, 1999a, 1999b) of the effects observed.

While examination of the clinical significance of the effects of BFST in families of children with diabetes has been limited, emerging evidence supports such change. Harris and colleagues (2001) presented results from a randomized clinical trial with BFST, in which they demonstrated clinically significant change in a variety of relevant domains. However, previous research on psychosocial treatment for youth with diabetes, including Harris et al. (2001), sampled a broad range of families and has not focused on the effectiveness of BFST with high-need samples, such as youth with poorly controlled diabetes and youth not regularly attending clinic visits. Specific attention to this subset of patients is critical because they tend to experience higher rates of hospitalization, require a significant amount of effort from medical providers (Harris & Mertlich, 2003), and often evidence a wide variety of psychosocial problems (LaGreca, Madigan, & Klemp, 1987). Determining whether empirically supported treatments such as BFST produce clinically relevant changes in this population is important for better understanding the parameters that affect treatment effectiveness. Preliminary analyses suggest that BFST may produce better effects on

family conflict and treatment adherence for youth with diabetes that is poorly controlled (Wysocki et al., 2006, 2007), though more work is needed to investigate whether changes are clinically significant. Determining whether BFST can produce clinically significant change in this high-needs pediatric population also has implications for understanding clinical significance in pediatric psychology more broadly. As the literature on clinical significance develops, it will be critical to attend to whether clinically significant results can be obtained in samples that include a broader range of high-risk participants, as this is essential in the translation of this research into broader clinical settings.

This study aimed to determine whether home-based BFST (Harris & Mertlich, 2003) produced clinically significant change in family conflict with a sample of adolescents with poorly controlled diabetes and their families. To accomplish this, the magnitude of the effects of intervention was examined. Glass' delta (Glass, 1976) was used to calculate mean standard deviation differences for scores on measures of diabetes-related conflict and general family conflict, to determine the degree of change. Differences from participants in the current study were compared with data from a demographically similar sample of youth who did not receive the treatment. We hypothesized that participation in home-based BFST would result in clinically significant decreases in reported diabetes specific and general parent-adolescent conflict.

Methods

Participants

BFST Treatment Group

Eighteen adolescents with diabetes between 13 and 18 years of age and their primary caregiver(s) received BFST. Inclusion criteria for adolescents included: (a) chronically poor metabolic control as demonstrated by two or more consecutive HbA1c values at or above 9.0% or (b) a history of two or more missed clinic appointments within the past year with their most recent HbA1c value at or above 9.0%. HbA1c levels at or above 9.0% was chosen as the cut-off based on overall clinic data (mean HbA1c 8.5%) and consultation with medical providers (Dr Neil H. White, personal communication). An HbA1c of 9.0% translates into a blood glucose level (BGL) of 210 (Nathan et al., 2008). The ADA target BGL range in youth with diabetes is 80 to 180. Thus, utilizing 9.0% as the cut-off for the study translated into a focus on individuals with consistent BGLs outside of the recommended target. In actuality, mean HbA1c levels in both the treatment (11.4%) and

Table I. Demographics of Treatment (BFST) and Comparison Group

	BFST group	Comparison group
N	18	40
Mean age (years)	16.0 (0.9)	15.2 (1.5)
Duration of diabetes (years)	6.2 (3.8)	4.8 (3.2)
Mean HbA1c		
Baseline:	11.4 (1.4)	11.1 (1.6)
Posttreatment	11.1 (1.4)	
Race (%)		
African American	33	47
Caucasian	67	53
Gender (%)		
Female	33	55
Male	67	45
Family composition (%)		
Single parent	33	44
Hollingshead Index Distribution (in frequency)		
Major professional	1	5
Minor professional	8	14
Clerk or Sales	6	7
Semi-skilled	3	14

comparison groups (11.1%) were notably higher than the 9.0% cut-off and represented BGLs of approximately 275.

Recruitment resulted in 45% of eligible families enrolled ($n = 18$) with 55% declining to participate ($n = 22$). The most common reasons given for declining included (a) too much of a time commitment, (b) not wanting someone to come to their home, and (c) not interested in family therapy. Sample demographics are presented in Table I. The final sample included 16 youth with T1DM (89%) and 2 with T2DM (11%); all youth with Type 2 diabetes required multiple daily insulin injections. Participants had a mean age of 16.0 years ($SD = 0.5$), mean duration of diabetes of 6.2 years ($SD = 3.8$), and a mean baseline HbA1c of 11.3% ($SD = 1.5\%$) all with a 12-month history of HbA1c values at or above 9.0%. Participants included a large percentage of African-American adolescents (33%), adolescents from single-parent homes (33%), and adolescents from middle and lower socioeconomic families (94%, based on Hollingshead Four Factor Index scores; Hollingshead, 1975). The study sample was similar demographically to families that declined to participate with the exception of greater numbers of African-American adolescents and adolescents from single-parent homes in the study sample compared to those who declined. HbA1c levels in the treatment group were similar to the levels of those adolescents whose families declined to participate (10.2%), yet higher than the general clinic population HbA1c of 8.5%. Fifty percent of adolescents

in the study had missed two or more clinic visits within the past 12 months.

Comparison Group

Comparison group data included baseline data obtained as a part of a randomized controlled trial examining two variants of BFST (Wysocki et al., 2006, 2007). The comparison group included 40 adolescents with diabetes and their families who were recruited from two sites, one in the Midwest and the other in the Southeastern United States. Adolescents participating in this study had a mean age of 15.2 years ($SD = 1.5$), mean duration of diabetes of 4.8 years ($SD = 3.2$), and a mean baseline HbA1c of 11.0% ($SD = 1.6\%$), all with a 12-month history of HbA1c values at or above 9.0%. The sample included 39 youth with T1DM (98%) and 1 with T2DM (2%). Youths and parents in the comparison group had yet to receive any psychosocial treatment as a part of their involvement in the study. Comparisons of the BFST treatment group and the comparison group indicated that the samples were demographically similar with the exception of the comparison group being made up of significantly more African-American families (Table I).

Procedures

All study procedures were approved by the Institutional Review Boards at Washington University School of Medicine in St Louis, Missouri and Nemours Children's Clinic in Jacksonville, Florida. Adolescents and parents identified for participation in the BFST treatment group were contacted by phone or during their clinic visit for recruitment. If the adolescents and their parents agreed to participate, arrangements were made for the parents of the adolescent to complete an informed consent and the adolescent was asked for his/her assent. After obtaining informed consent/assent, adolescents and their parents completed a baseline evaluation that included a number of paper-and-pencil questionnaires assessing psychosocial, behavioral, and family functioning. Similar follow-up evaluations occurred immediately after treatment (approximately 6–10 weeks from baseline). Families received \$50 for the completion of the baseline and follow-up evaluations.

Treatment

Families received 10 1.5-hr sessions of home-based version of BFST (Robin & Foster, 1989) over a period of approximately 5–8 weeks. All primary adult care givers participated in each session which included biological/adoptive/step mother and father, single mother or father, or grandparents/other adult family members. Sessions were

conducted by a master's level social worker or a doctoral level psychologist in-training with extensive training from the principal investigator (PI) in diabetes management and BFST. Training included 40 hr of role playing, providing BFST to practice families of adolescents without diabetes, and review of video of the PI conducting BFST. Therapists were trained in BFST using the manual produced by the first author and colleagues for use with adolescents with chronic illnesses (Wysocki, Harris, Greco, Mertlich, & Buckloh, 2001). The study was completed prior to the development of the BFST-D model which is generally the same as the BFST model, but has a heavier emphasis on diabetes-related conflict and includes a parent simulation of diabetes along with instruction in monitoring of blood glucose levels and patterns. Extensive efforts were taken to ensure proficient implementation of BFST; each therapy session was videotaped and reviewed by the PI, and weekly supervision sessions with therapists were conducted (Harris & Mertlich, 2003).

BFST consists of four therapy components that are used in accord with each family's needs as identified by their responses to the questionnaires completed at baseline: problem-solving training, communication skills training, cognitive restructuring, and functional/structural family therapy (Wysocki et al., 2001; see Supplementary Material). All components of BFST address problems related to the adolescent's diabetes as well as more general issues.

Measures

Diabetes Responsibility and Conflict Scale

The Diabetes Responsibility and Conflict Scale (DRC) is a 30-item instrument designed to assess parent-child divisions of diabetes-related responsibility (15 items) and diabetes-related family conflict (15 items) surrounding diabetes tasks in the past month (Rubin, Young-Hyman, & Peyrot, 1989); higher scores indicate greater conflict. Due to our focus solely on diabetes-related conflict and not responsibility for diabetes management, only the 15-item conflict subscale was used for the purposes of this study. The internal consistency for the DRC mother report was .72 and .93 for the adolescent report; and for the comparison sample the internal consistency for the DRC mother report was .84, .89 for father report, and .87 for the adolescent report.

Conflict Behavior Questionnaire

The Conflict Behavior Questionnaire (CBQ) is a 20-item true/false scale that assesses general conflict between parents and their children, with higher scores indicating greater conflict. The CBQ was completed by parents and

adolescents at baseline and immediately following treatment. The CBQ has been used extensively to assess family interactions, including with families of youth with psychiatric conditions (Esposito-Smythers et al., 2006), traumatic brain injury (Wade, Michaud, & Brown, 2006), and diabetes (Harris, Greco, Wysocki, Elder-Danda, & White, 1999). Internal consistency for the CBQ in the treatment sample was .88 for mother report, .87 for father report, and .92 for adolescent report and in the comparison group .89 for mother report, .85 for father report, and .91 for adolescent report. Research has demonstrated that the CBQ discriminates between distressed and nondistressed families (Prinz, Foster, Kent, & O'Leary, 1979).

HbA1c

During the baseline and posttreatment evaluations blood was collected for determination of HbA1c using the DCA2000 method. HbA1c is a reliable and accepted measure of diabetic control over the previous few months, and the DCA2000 method correlates well with the high pressure liquid chromatography method used by the DirectNet Study (DirectNet, 2005).

Analyses

A social comparison technique was used to assess the clinical significance of in-home BFST in decreasing diabetes-related conflict and general parent-adolescent conflict between adolescents with diabetes and their parents. This technique involves (a) obtaining data from a normative sample on a criterion measure used to assess treated subjects, (b) subtracting the mean from the normative group from the pre- and post-treatment mean on the criterion measure, and (c) dividing by the standard deviation of the normative group on the criterion measure. Effect sizes are expressed as *z*-scores and involve the following computation: $(M_t - M_c)/SD_c$ where M_t = treatment group mean, M_c = control group mean, and SD_c = control group standard deviation (Kendall, 1984). The resulting value represents a *z*-score from which Glass' delta can be calculated to estimate the degree of change or clinical significance of the change by subtracting the pre- and post-treatment *z*-scores from one another. This technique has been used and advocated in previously published studies examining the effect of psychotherapy (Henson, 2006; Jacobson, Follette, & Revenstorf, 1984; Neitzel & Trull, 1988; Trull, Nietzel, & Main, 1988; Weisz, Donenberg, Han, & Weiss, 1995).

Although there are many effect-size indices, Henson (2006) proposes the use of one of two effect size indices (Cohen's *d* and Glass' delta) based on the questions being

asked about the findings. If national normative data exists for the outcomes under study then the use of *T*-scores and *T*-score standard deviations would be the most appropriate values from which to calculate mean differences. Since many psychosocial outcome measures lack national normative data (Rodrigue, Geffken, & Streisand, 2000), it is necessary to use indices such as Cohen's *d* or Glass' delta in the calculation of effect sizes and mean differences. Cohen's *d* (Cohen, 1988) uses a pooled estimate of the treatment and control group standard deviations, while Glass' delta involves using just the control group's standard deviation. Glass' delta would be the index of choice when it is expected that the treatment may affect both the treatment mean and the treatment standard deviation (Glass, 1976). In addition, while the effect size or in this case delta is thought of as being independent of the control and experimental groups' sample sizes, uneven sample sizes can cause substantial understatement of the relationship between the independent and dependent variables (Hunter, 2004). Previous research has shown that BFST changes both the treatment mean and treatment standard deviation on outcome variables related to parent-adolescent conflict (Wysocki et al., 2001), supporting the use of Glass' delta in the current study.

Results

Prior to treatment, the mean DRC score for adolescents in the treatment group was 0.57 *SD* below that of the comparison group. This placed adolescents in the treatment group in the 29th percentile on the DRC prior to treatment (higher percentile scores indicate higher diabetes-related conflict). Eighteen mothers and 12 fathers in the treatment group and 22 mothers and 18 fathers in the comparison group completed questionnaires. Mean DRC score for mothers in the treatment group was approximately 0.58 *SD* below that of the comparison group placing mothers in the treatment group in the 28th percentile on the DRC prior to treatment. Mean DRC treatment group score for fathers was 0.82 *SD* below the mean (20th percentile). Consequently, adolescents, mothers and fathers in the treatment group scored lower than the comparison group on the DRC prior to treatment, indicating lower mean levels of conflict (Table II).

Mean posttreatment DRC scores for adolescents, mothers and fathers in the treatment group were all lower than at pretreatment, -1.00 , -1.01 , and -0.87 respectively; pre- to post-treatment DRC scores for adolescents and mothers were statistically significant. Based on the criterion of 1.0 *SD* mean difference, the DRC

Table II. Comparison of DRC Treatment and Comparison Group Scores for Adolescents, Mothers, and Fathers

Respondents & Evaluation	BFST group Mean (SD)	<i>t</i>	Comparison group Mean (SD)	ES (CI)	Δ
Adolescents					
Pretreatment	30.7 (15.0)			-.57	
Posttreatment	25.4 (12.8)	3.59**	37.7 (12.3)	-1.00	.43
				(-1.56 to -0.39)	
Mothers					
Pretreatment	29.7 (15.0)			-0.58	
Posttreatment	23.9 (6.9)	2.50*	37.6 (13.5)	-1.01	0.43
				(-1.73 to -0.54)	
Fathers					
Pretreatment	27.1 (8.1)			-.82	
Posttreatment	26.6 (7.6)	0.83	36.3 (11.2)	-.87	0.05
				(-1.52 to -0.35)	

* $p < .05$; ** $p < .01$.

Higher scores indicate higher conflict.

ES = effect size; CI = confidence intervals.

Table III. Comparison of CBQ Treatment and Comparison Group Scores for Adolescents, Mothers, and Fathers

Respondents & Evaluation	BFST group Mean (SD)	<i>t</i>	Comparison group Mean (SD)	ES (CI)	Δ
Adolescents					
Pretreatment	6.1 (5.7)			-.09	
Posttreatment	4.5 (4.5)	2.30*	6.6 (5.5)	-.38	.29
				(-0.96-0.16)	
Mothers					
Pretreatment	9.5 (4.7)			.36	
Posttreatment	5.1 (5.0)	2.27*	7.3 (6.1)	-.36	.72
				(-0.94-0.19)	
Fathers					
Pretreatment	9.9 (6.1)			.41	
Posttreatment	6.8 (7.2)	2.11*	7.3 (6.3)	-.07	.48
				(-0.63-0.48)	

* $p < .05$.

Higher scores indicate higher conflict.

posttreatment standard deviation differences were moderate for adolescents ($-.43$ *SD*) and mothers ($-.43$ *SD*), and largely nonexistent for fathers (-0.05 *SD*).

Results indicate that prior to treatment the mean CBQ score for adolescents in the treatment group was approximately 0.09 *SD* below that of the comparison group. This placed adolescents in the treatment group on the CBQ in the 45th percentile prior to treatment (higher percentile scores indicate higher general parent-child conflict). Conversely, the mean CBQ score for the mothers in the treatment group was approximately .36 *SDs* above that of the comparison group. This placed mothers in the treatment group above the 63rd percentile on the CBQ prior to

treatment. Finally, the mean CBQ treatment group score for fathers was .41 *SDs* above the mean (66th percentile). Consequently, the adolescents in the treatment group scored similarly to that of the comparison group on the CBQ prior to treatment while the mothers and fathers scored somewhat higher (Table III).

Mean posttreatment CBQ scores for adolescents, mothers and fathers in the treatment group were all lower than at pretreatment, $-.38$, $-.36$, and $-.07$ respectively; change in all scores was statistically significant. Based on the criteria of 1.0 *SD* mean difference, the CBQ posttreatment standard deviation differences were minimal for adolescents (.29 *SD*) and more moderate for mothers (.72 *SD*) and fathers (.48 *SD*). There were no differences in either baseline functioning or treatment effectiveness by ethnicity.

Correlations between HbA1c levels and measures of family conflict at baseline (both groups) and posttreatment (treatment group) were non-significant. Using a within-subject analytic approach, previously published results indicate that no statistically significant change in HbA1c levels was obtained for the treatment group following participation in the home-based version of BFST (Harris & Mertlich, 2003); thus, no test of clinical significance was conducted for this variable.

Discussion

Current findings suggest that BFST resulted in improvements in mother and adolescent reported diabetes-specific conflict, as well as parent-reported general parent-adolescent conflict. This study is unique in that it demonstrated the application of an empirically supported treatment in a sample of youth with diabetes who presented notable challenges including poor health status, irregular attendance to clinic appointments, and psychosocial variables (e.g., single-parent homes) that increase the risk of difficulties following prescribed complex medical regimens. In addition, this study demonstrates the implementation of an empirically supported treatment in applied settings (i.e., the family's home and neighborhood). These demonstrations represent an important contribution to the literature on interventions for psychosocial issues for youth with diabetes given that few if any studies have been conducted exclusively with youth who evidence the multiple challenging risk factors present in the current sample (Ellis et al., 2005).

Our emphasis on a pediatric population with multiple challenges is consistent with other research relevant to the investigation of the effectiveness of psychosocial

treatments. For example, in their studies investigating the effectiveness of a group intervention for encopresis, Stark and colleagues (Stark et al., 1997; Stark, Owen-Stively, Spirito, Lewis, & Guevremont, 1990) enrolled only children who had previously failed to respond to medical treatment alone. As Kazdin (1999a) pointed out, often participants in controlled investigations have fewer or less severe issues than youth seen in pediatric practices. This limits the generalizability of any treatment effects to general clinical practice (Drotar, 2002). Our investigation focused exclusively on youth presenting with clinically relevant poor health status (i.e., mean HbA1c levels 11%) and/or health behaviors (i.e., poor adherence to prescribed medical care), youth and families who are most likely in need of ancillary intervention to improve health status. As such, *while not an investigation of clinical effectiveness per se*, this study contributes to the growing emphasis on clinically *meaningful outcomes* in pediatric psychology.

Further, this study demonstrates the use of social comparison to assess clinical significance of an intervention. Drotar (2002) highlighted the need to extend evaluation of empirically-based treatments in pediatric psychology beyond null hypothesis significance testing (NHST) given that NHST relies on examining the efficacy of psychosocial interventions and limits our ability to determine which treatments work in real clinical practice (Weisz, 2000). This study demonstrates one method for moving beyond NHST toward a model that evaluates the value of the findings that family therapy with adolescents with diabetes improves health-related and general functioning. Weisz (2000) suggested that by using alternatives to NHST, clinicians are able to determine if an intervention, like the one used in this study, produces meaningful change for those receiving treatment. In this particular case, for adolescents with poorly controlled diabetes and their parents, BFST produced both statistically significant changes in diabetes-related conflict and general family conflict based on NHST (Harris & Mertlich, 2003) and moderate effects based on a test of clinical significance. The case for clinical significance is enhanced by previous research suggesting that changes in family conflict have important implications for treatment adherence and metabolic control (Anderson et al., 1981; Gustafsson et al., 1987; Hauser et al., 1990; Miller-Johnson et al., 1994; Wysocki, 1993). It should be noted that BFST did not produce statistically significant changes in HbA1c levels in the treatment group. This may be due to a variety of factors, most likely the fact that BFST rather than BFST-D was used. BFST-D has shown to result in greater changes in treatment adherence and metabolic control

(Harris, Wysocki, Buckloh, Oelbaum, & Antal, 2006; Wysocki et al., 2006, 2007).

The methodology used in the current study is an interesting approach to studying interventions with pediatric populations. Specifically, use of data from a relevant comparison group for calculation of effect sizes demonstrates that researchers with access to smaller numbers of participants are still able to attend to issues relevant to clinical significance. Normative data do not exist for many outcome measures used in pediatric psychology (Rodriguez et al., 2000). Thus, determining whether participants move from the clinically elevated to normative range on those outcome measures is not possible, a method recommended for attending to clinical significance of changes (Kendall, Marrs-Garcia, Nath, & Sheldrick, 1999). Methods used in the current study demonstrate a test of significance using two other recommended methods: (a) comparison with pretreatment samples and (b) evaluating the social impact, or the degree to which the intervention affected variables of relevance for families (Kazdin, 1999a, 1999b).

Findings from the present study indicate that a home-based application of BFST implemented with a sample of youth with diabetes with a host of psychosocial and medical challenges can attenuate diabetes-related and general family conflict between youths with diabetes and their parents such that those improvements represent clinically meaningful change. Posttreatment scores on diabetes-related conflict for adolescents and mothers participating in BFST were significantly lower than pre-treatment scores based on NHST; however, the magnitude of change was marginally meaningful for both adolescents and mothers (e.g., $1/2$ *SD* improvement). For example, adolescents and mothers in the treatment group evidenced a 0.43 *SD* mean difference on diabetes-related conflict from pre- to post-treatment.

The findings from the general family conflict data were more definitive in demonstrating that participation in BFST can result in meaningful change for families with multiple psychosocial stressors. For example, posttreatment scores on general parent-adolescent conflict for adolescents, mothers and fathers participating in BFST were significantly lower than pretreatment scores utilizing NHST (Harris & Mertlich, 2003). The magnitude of change from pre- to post-treatment CBQ scores was more substantial for mothers (i.e., $3/4$ *SD*) and less so for adolescents ($1/3$ *SD*) and fathers ($1/2$ *SD*). Given the strong association between family conflict and poorer metabolic control and adherence to treatment in youth with diabetes (Anderson et al., 1981; Gustafsson et al., 1987; Hauser et al., 1990; Miller-Johnson et al., 1994; Wysocki, 1993), as well as

evidence that improvements in family conflict and treatment adherence and metabolic control may cooccur following implementation of BFST (Wysocki et al., 2006), documented changes in family conflict with participants with a host of psychosocial challenges are clinically relevant. In fact, significant improvement in adherence by the adolescents receiving BFST in the current study following treatment has been reported previously (Harris & Mertlich, 2003). Reduction in family conflict has the potential for reducing the overall burden for families in their day-to-day lives and/or changing the quality of interactions around diabetes management in very difficult families. In addition, improvements in diabetes management and health outcomes related to a reduction in family conflict are likely to emerge much slower than observed changes in family conflict and as such, addressing family conflict continues to be a reasonable starting point for many of these families.

Reasons for differential effects across mothers and fathers in diabetes-specific conflict are unclear, though speculation is appropriate. The number of participating fathers was small, and thus the ability to detect effects with fathers may have been limited. Further, the baseline DRC score was lower for fathers than mothers, and thus a basal effect may be in place. Alternatively, it may be that participating fathers were less engaged in management of the youth's diabetes, as research has shown fathers tend to be less involved than mothers in the management of pediatric chronic medical conditions (Quittner, Opirpari, Regoli, Jacobsen, & Eigen, 1992; Wysocki & Gavin, 2004). Additional research is needed to better understand this finding.

Several limitations of this study should be considered. First, there is controversy regarding the magnitude of change needed to demonstrate clinically significant change. The change observed in diabetes-related conflict scores for each family member was no more than $1/3$ a *SD* and no more than $3/4$ of a *SD* for general family conflict. Jacobson et al. (1984) advocated a change of at least 2.0 standard deviations to demonstrate clinical significance. However, Prentice and Miller (1992) suggested that a large effect does not necessarily indicate that the effect is of clinical value. Instead, they argued that one must consider how difficult it is to influence the dependent variable. Because research demonstrates the ubiquitous nature of family conflict in families of adolescents with and without diabetes (Arnett, 1999; Prinz, et al. 1979; Viikinsalo, Crawford, Kimbrel, Long, & Dashif, 2005), one could argue that even small improvements in family conflict are of clinical value.

Second, some may argue that the aforementioned finding should be interpreted cautiously given that the change

observed may reflect regression to the mean. Evidence for possible regression to the mean is supported by the higher value of the pretreatment CBQ means for the treatment group in contrast to that of the comparison group means for adolescents, mothers, and fathers. Thus, any posttreatment scores could be interpreted as the pretreatment scores regressing to the mean. Although not presented here, previously published research examining follow-up data from this study indicated that the CBQ means at a 6-month follow-up were closer approximations of the pretreatment means than the posttreatment means (Harris, Harris, & Mertlich, 2005). Consequently, it is unlikely that the posttreatment results reflect regression to the mean.

Third, sample sizes for both groups were relatively small. The obvious limitations of small sample sizes certainly apply to this study including limits on generalizability, weaker inferences with smaller samples, and the unlikelihood that the sample average follows a normal distribution. Sample size also limits the ability to investigate additional demographic variables (e.g., gender, family composition) that might influence effects of BFST. On a related note, it is possible that the lower DRC scores in the treatment group at baseline were the result of a smaller sample size with less heterogeneity. Despite these potential limitations, there are virtues of small sample sizes one of which allows for the closer scrutiny of fewer cases which can allow for a clearer understanding of the findings (Pruzek, 2005).

Fourth, a relatively low recruitment rate was obtained for the treatment group. Reasons given for nonparticipation suggest that the BFST therapy model may be overly burdensome for some families. This suggests some limitations in disseminating treatment to the population of youth with poorly controlled diabetes. However, these and other published data on BFST (Wysocki et al., 2006, 2007) support the benefit of this treatment for families who receive it. In addition, given the chaotic nature of the families participating in this study and the fact that many had not been in for their quarterly diabetes visits for a year or more, to recruit and retain 45% of the eligible subjects is remarkable.

Fifth, due to a small number of participants with T2DM, individuals with both T1DM and T2DM were examined together. While this limits the ability to speak about either group independently, it seems that, given the severity of all cases and the similarity in treatment regimens, the impact of collapsing across these groups should be minimal. That said, it may be fruitful for future research to consider how disease type may impact the clinical significance of similar treatments.

Finally, only two outcome measures were used to determine clinically significant change; thus future examinations of clinically significant change in similar studies should involve the use of multiple outcome measures. Additional variables that need to be considered in determining the value of family therapy with adolescents with poorly controlled diabetes include the cost of BFST and the psychosocial and financial costs of leaving patients untreated.

Despite the aforementioned limitations, this study supports the use of BFST as a meaningful and useful treatment for families of adolescents with poorly controlled diabetes who are experiencing heightened levels of family conflict. Although an examination of the feasibility of BFST was not conducted, BFST is a skill-based intervention that can easily be delivered in the clinic, it has been demonstrated in other studies to be socially valid (Wysocki et al., 1997), and the overall cost of 10 sessions of BFST estimated at \$3,000 (Harris & Mertlich, 2003) is much less than the estimated \$10,000 spent for one admission to the hospital for diabetic ketoacidosis or poorly controlled diabetes (Maldonado, Chong, Oehl, & Balasubramanyam, 2003). Please note that, although the participants in this study had a history of repeated hospitalization for ketoacidosis, none were hospitalized for ketoacidosis or other diabetes-related problems during the course of the investigation. Variability in the ability to be reimbursed for either home-based or clinic-based application of BFST that exists across insurance companies will continue to influence accessibility of this type of treatment. However, this is not an issue unique to BFST, but rather to any psychosocial/mental health treatment. Given the high frequency with which family therapy is being used for youth with chronic health problems, the clinical implications of this study suggest that BFST should be considered as an effective treatment option for adolescents with chronically poor metabolic control.

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Supplementary Data

Supplementary data are available at *JPEPSY* online.

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