Child- and Family-Focused Cognitive-Behavioral Therapy for Pediatric Bipolar Disorder: A Randomized Clinical Trial

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Objective: Previous studies have found that family-based psychosocial treatments are effective adjuncts to pharmacotherapy among adults and adolescents with bipolar disorder (BD). The objective of this study was to compare the efficacy of adjunctive child- and family-focused cognitive-behavioral therapy (CFF-CBT) to psychotherapy as usual (control) for mood symptom severity and global functioning in children with BD. **Method:** Sixty-nine youth, aged 7 to 13 years (mean = 9.19, SD = 1.61) with *DSM-IV-TR* bipolar I, II, or not otherwise specified (NOS) disorder were randomly assigned to CFF-CBT or control groups. Both treatments consisted of 12 weekly sessions followed by 6 monthly booster sessions delivered over a total of 9 months. Independent evaluators assessed participants at baseline, week 4, week 8, week 12 (posttreatment), and week 39 (6-month follow-up). **Results:** Participants in CFF-CBT attended more sessions, were less likely to drop out, and reported greater satisfaction with treatment than controls. CFF-CBT demonstrated efficacy compared to the control treatment in reducing parent-reported mania at posttreatment and depression symptoms at posttreatment and follow-up. Global functioning did not differ at posttreatment but was higher among CFF-CBT participants at follow-up. **Conclusion:** CFF-CBT may be efficacious in reducing acute mood symptoms and improving long-term psychosocial functioning among children with BD. J. Am. Acad. Child Adolesc. Psychiatry, 2014;■(■):■–■. **Key Words:** pediatric bipolar disorder, cognitive-behavioral therapy, family-focused intervention, randomized clinical trial

Pediatric bipolar disorder (PBD) describes bipolar spectrum illness among children and preadolescents. Affecting approximately 1% to 2% of the population,[1] PBD is characterized by extreme episodic mood dysregulation accompanied by symptoms (e.g., decreased need for sleep, hypersexuality, impulsivity) that significantly impair multiple domains of functioning. PBD is differentiated from adult-onset bipolar disorder (BD) by increased rates of rapid cycling, mixed mood states, psychiatric comorbidity, and developmentally-specific psychosocial impairment.[2,3] Compared to healthy peers, children with PBD demonstrate neurocognitive deficits, poor academic performance,[4,5] and disruptive school behavior.[6] Peer relationships are characterized by limited peer networks, peer victimization, and poor social skills.[7,8] Compared to families that are not affected by PBD, family functioning is often characterized by strained relationships,[8,9] low levels of cohesion, and increased conflict;[10-12] in addition, family stress and dysfunction increase with symptom levels.[13,14] The accumulation of psychosocial risk renders PBD a significant public health concern as evidenced by high rates of repeated hospitalization and suicide attempts.[15] In adulthood, people with BD demonstrate greater mental health care use, elevated rates of other health conditions, lower rates of graduation, and decreased career productivity.[15-17] Recent data from the World Health Organization indicate that BD is the fourth leading cause of disability in youth ages 10 to 24 years worldwide.[18]

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Pharmacotherapy is the first-line treatment for PBD but is complicated by low response rates, poor tolerability,[19] and inability to address the full range of impairments associated with PBD. Thus, adjunctive psychosocial intervention is considered essential for effective treatment.[20] Despite this, few psychosocial treatments for youth with BD have been studied systematically. Adaptations of dialectical behavior therapy (DBT)[21] and interpersonal and social rhythm therapy (IPSRT)[22] for adolescents with BD have been tested in pilot studies. However, only 2 interventions have demonstrated efficacy in randomized controlled trials (RCT): multi-family psycho-education group psychotherapy (MF-PEP) for youth with BD or unipolar depression in children aged 8 to 12 years,[23] and family-focused treatment (FFT) for adolescents aged 13 to 18 years.[24] These treatments demonstrated effects on mood severity in children[23] and depression relapse in adolescents,[24] respectively. It is not yet known whether a treatment model such as child- and family-focused cognitive-behavioral therapy (CFF-CBT), which more specifically targets the unique symptoms and impairments in childhood BD, will improve outcomes compared to these other treatments.

CFF-CBT was developed to target the unique developmental needs of the PBD population in a comprehensive family-focused format. CFF-CBT integrates CBT with psychoeducation and complementary mindfulness-based and interpersonal/family therapy techniques tailored to address the range of therapeutic needs in families affected by PBD. The components of CFF-CBT are driven by 3 areas of research: developmentally specific symptoms of PBD (e.g., rapid cycling, mixed mood states, comorbid disorders); affective circuitry brain dysfunction in PBD (e.g., poor problem-solving during affective stimulation via ventral frontostriatal and dorsolateral prefrontal circuitry dysfunction and deficits in superior temporal and visual cortices)[25-27]; and the impact of PBD on interpersonal/family functioning. CFF-CBT is delivered via 12 manualized weekly 60- to 90-minute sessions with the child, parent, and/or family. It includes 7 components that comprise the treatment acronym "RAINBOW": Routine (developing consistent daily routines); Affect Regulation (psychoeducation about feelings; mood monitoring; coping strategies to improve mood regulation); I Can Do It! (improving child self-esteem and parent self-efficacy); No Negative Thoughts/Live in the Now (cognitive restructuring and mindfulness techniques to reduce negative thoughts); Be a Good Friend/Balanced Lifestyle (social skill-building and improving parent self-care); Oh How Do We Solve this Problem? (family problem-solving and communication training); and Ways to Find Support (enhancing support networks; detailed in Pavuluri *et al.*[28]).

This was the first RCT testing the efficacy of CFF-CBT in treating PBD. Open trials have established the feasibility, acceptability, and preliminary efficacy of CFF-CBT with promising outcomes.[28-30] The goal of this trial was to test the efficacy of the individual family format of CFF-CBT compared to that in patients receiving psychotherapy as usual (control) on outcomes of symptom control and global functioning. We hypothesized that CFF-CBT would improve the symptoms and global functioning of children at posttreatment compared to the control condition. We also hypothesized that treatment effects would be maintained at follow-up, evidenced by differences in longitudinal trajectories of symptoms and functioning from baseline through the follow-up assessment point.

METHOD

Study Participants

Participants were children (N = 69) diagnosed with PBD recruited from a specialty pediatric mood disorders clinic (PMDC) in an urban academic medical center between 2010 and 2013. Children meeting *DSM-IV-TR* criteria for bipolar spectrum disorders (BD-I, II, and not otherwise specified [BP-NOS]) aged 7 to 13 years were eligible to participate. Inclusion criteria encompassed the following: stabilization on medication, parental consent, and youth assent. Stabilization on medication was defined by a Young Mania Rating Scale (YMRS)[31] score $\leq$20 and Children's Depression Rating Scale–Revised (CDRS-R)[32] score <80 (indicating no severe symptoms requiring immediate more intensive care). These criteria were intended to exclude children who needed acute stabilization before being able to participate in psychotherapy but to still include children who were actively symptomatic. Thus, children scoring above threshold on these measures (n = 4) were included if their psychiatrist determined they were stable enough to engage in treatment. Exclusion criteria for the study included: youth IQ <70, as measured by the Kaufman Brief Intelligence Scale–2 (KBIT-2[33]), active psychosis, active substance abuse/dependence, neurological or other medical problems that significantly complicate child's psychiatric symptoms as assessed via the Washington University Schedule for Affective Disorders and Schizophrenia (WASH-U-KSADS[34]), and active suicidality requiring