A Randomized Clinical Trial of an Integrative Group Therapy for Children With Severe Mood Dysregulation

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Objective: Nonepisodic irritability is a common and impairing problem, leading to the development of the diagnoses severe mood dysregulation (SMD) and disruptive mood dysregulation disorder (DMDD). No psychosocial therapies have been formally evaluated for either, with medication being the most common treatment. This study examined the feasibility and efficacy of a joint parent–child intervention for SMD.

Method: A total of 68 participants aged 7 to 12 years with attention-deficit/hyperactivity disorder (ADHD) and SMD were randomly assigned to the 11-week therapy or community-based psychosocial treatment. All participants were first stabilized on psychostimulant medication by study physicians. Of the participants, 56 still manifested impairing SMD symptoms and entered the therapy phase. Masked evaluators assessed participants at baseline, midpoint, and endpoint, with therapy participants reassessed 6 weeks later.

Results: All but 2 therapy participants attended the majority of sessions (n = 29), with families reporting high levels of satisfaction. The primary outcome of change in mood symptoms using the Mood Severity Index (MSI) did not reach significance except in the subset attending the majority of sessions (effect size = 0.53). Therapy was associated with significantly greater improvement in parent-rated irritability (effect size = 0.63). Treatment effects for irritability but not MSI diminished after therapy stopped. Little impact on ADHD symptoms was seen. Results may not be generalizable to youth with SMD and comorbidities different from those seen in this sample of children with ADHD, and are limited by the lack of a gold standard for measuring change in SMD symptoms.

Conclusion: While failing to significantly improve mood symptoms versus community treatment, the integrative therapy was found to be a feasible and efficacious treatment for irritability in participants with SMD and ADHD.

Clinical trial registration information—Group-Based Behavioral Therapy Combined With Stimulant Medication for Treating Children With Attention Deficit Hyperactivity Disorder and Impaired Mood; http://clinicaltrials.gov/; NCT00632619.

Key words: severe mood dysregulation, disruptive mood dysregulation disorder, ADHD, psychosocial treatment, group therapy

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There has been increasing recognition that many children with attention-deficit/hyperactivity disorder (ADHD) exhibit nonepisodic irritability and deficits in emotion regulation.[1-3] Although not found to be at increased risk for bipolar disorder (BD),[4] children with nonepisodic irritability have elevated rates of other internalizing disorders.[4,5] For instance, they have a 7-fold greater risk for major depressive disorder (MDD).[6] These children also exhibit high rates of aggression and are more impaired compared to children with ADHD and oppositional defiant disorder (ODD).[7-10] These impairments progress to a wide range of adverse outcomes in adulthood.[11] The National Institute of Mental Health (NIMH) created the construct of "severe mood dysregulation" (SMD) to study youth with persistent irritability, excessive reactivity to stimuli, and hyperarousal. The SMD criteria were slightly modified for the *DSM-5*[12] to create the diagnosis of disruptive mood dysregulation disorder (DMDD), eliminating the hyperarousal criteria and sadness as a qualifying abnormal interval mood.

Little is known about the treatment of SMD.[2,13] The only controlled medication trial found no benefit of lithium over placebo.[14] The lack of evidenced-based interventions for nonepisodic irritability has been linked to the increased prescribing of antipsychotics to youth with ADHD.[15,16] It has been suggested that increased use of psychosocial interventions may decrease polypharmacy. Psychosocial treatments may at least serve as an adjunct that enhances outcomes at lower medication doses, as seen in schizophrenia.[17,18] Not surprisingly, there has been a call for psychosocial treatments tailored to address the most impairing symptoms seen in SMD, namely, temper outbursts and persistent irritablity.[13]

Behavioral parent training (BPT) is efficacious for improving ADHD, oppositional behaviors, and aggression.[19] However, BPT and psychostimulants have not proved

CG Clinical guidance is available at the end of this article.

sufficient to normalize functioning in youth with SMD and ADHD.[8,20] One reason for the limited efficacy may be that BPT does not address deficits in emotion regulation.[3] The addition of an emotion regulation component may be particularly essential for treatment of SMD, as the presence of high levels of externalizing symptoms predicts reduced efforts by parents to engage in emotion regulation coaching with their child.[21] Moreover, concerns have been raised that BPT programs addressing volitional temper outbursts may need to be modified for youth with prominent emotional lability, in recognition that these children experience sustained negative mood states that are difficult to voluntarily supress.[22]

Abnormal responses to frustration may drive the anger outbursts and persistent irritability seen in SMD. Once frustrated, youth with SMD experience excessive arousal[23,24] and state-dependent impairments in attentional flexibility.[25] They exhibit differential patterns of central nervous system (CNS) activation in response to negative feedback[13] and experience prolonged recovery from frustration that can be particularly impairing for peer relationships.[3,9] Because of these deficits, problem-solving efforts after the onset of prominent irritability may prove quite challenging. Therefore, it may be advisable to focus parental efforts on antecedent management and soothing of negative affect and to delay engaging the child in problem-solving efforts until the negative affective state has diminished. At the same time, parents must be conscientious not to inadvertently reward defiance.

Youth with SMD also have difficulty identifying negative emotions[26] and experience greater fear when viewing neutral faces.[27] These impairments in emotion processing have been theorized to cause the elevated rates of reactive aggression seen with SMD.[28] Social cognitive programs for reducing aggressive behaviors may be efficacious for SMD, as they emphasize affect monitoring as well as coping skills for managing anger. They also promote assessment of antecedents and potential consequences before action and address hostile attribution biases and other distortions that may promote aggression.[29,30] These techniques may be effective for targeting deficits in response reversal seen in SMD.[2,9] However, cognitive interventions for social skills deficits in youth with ADHD have not proved routinely efficacious, possibly because of executive functioning impairments.[3,31] Therefore, modifications to existing therapies may be necessary to optimize efficacy.

Parents play a critical role in the development of emotion regulation skills, and persistent negative family cycles are theorized to lead to deficits in emotion regulation.[3,21] Families of children with ADHD are particularly likely to engage in aversive and conflictual parenting response.[32] As parental emotion regulation skills affect the efficacy of parenting interventions in mood-labile youth, [21] inclusion of a parenting component promoting coaching of emotion regulation skills may be advisable for the treatment of SMD.

In creating a treatment tailored to the needs of children with ADHD and SMD, we integrated and modified established techniques from cognitive-behavioral therapy (CBT) for mood disorders, social cognitive programs for aggression, and BPT programs for oppositional behaviors to target the core SMD symptoms of temper outbursts and irritability.[33-35] As children with SMD exhibit a wide range of internalizing symptoms,[2,6,9] the treatment's impact on other mood symptoms was examined. In an open pilot trial of the therapy entitled AIM (ADHD plus Impairments in Mood), reductions in mood and behavioral symptoms were observed in 7 children with SMD.[36] Based on these promising results, a randomized trial comparing AIM plus ADHD medication versus community psychosocial treatment plus ADHD medication was conducted. As stimulant medications are a first-line treatment for ADHD that improves irritability,[20,37] both groups were stabilized on stimulant medication before baseline.

METHOD

The study was conducted in 2 separate cohorts because of the research center relocating in the middle of the study. Between cohorts, identical procedures and many of the same staff were used at each site. The study was approved by governing institutional review boards at both sites.

Participants

Eligible participants were 7 to 12 years of age and had the combined subtype of ADHD and SMD.[2] Both disorders were required, as it is youth with ADHD and behavioral dyscontrol who are being increasingly prescribed antipsychotic medications,[15,16] and most children with SMD drawn from clinical samples will have ADHD.[9,14,25] Exclusionary criteria included an IQ below 80, prominent traits of autism spectrum disorder, use of any nonstimulant psychotropic, bipolar I/II disorder, or psychoses. Children with suicidal ideation needing emergent treatment were excluded. Otherwise, mood/anxiety disorders or suicidal ideation were not exclusionary.

Procedures

Families were recruited through advertisement and referrals from local providers. Written consent was obtained from the parents. Participants gave assent. ADHD, ODD, and conduct disorder (CD) were assessed using the Disruptive Behavior Disorders Structured Parent Interview (DBD-I), which also queries about the frequency and severity of temper outbursts at home, school, and with peers.[38] It was completed by masters-level clinicians with 2-plus years of experience in assessing ADHD. ADHD was confirmed by teacher report using the DBD Rating Scale (DBD-RS), which assesses all *DSM-IV* symptoms of ADHD, ODD, and CD on a 0 to 3 scale.[39] The SMD symptoms of excessive reactivity to negative stimuli, persistent angry/sad mood, and hyperarousal, plus symptoms of other mood disorders were assessed using the mood modules from the Washington University in St. Louis Kiddie Schedule for Affective Disorders and Schizophrenia (WASH-U-KSADS) (Table 1). The WASH-U-KSADS asks about developmentally appropriate symptoms of mood disorders using probes designed to disentangle mood from ADHD symptoms.[40,41] These modules specifically query participants and parents about the frequency, severity, and duration of angry/sad moods and temper outbursts. Parent interviews were completed by MD/PhD staff and participant assessments by experienced graduate students. Integration of both reports along with relevant information gathered from the DBD-I was used to achieve a final composite score, with greater weight given to the reporter deemed most reliable on an item-by-item basis. All raters completed a systematic training course consisting of video reviews