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Emotion Regulation Intensive Outpatient Programming: Development, Feasibility, and Acceptability

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Abstract

Individuals with Autism Spectrum Disorder (ASD) and/or intellectual and developmental disabilities (DD) often struggle with behavior management and emotion-regulation (ER). In this manuscript, we describe the results of a chart review examining a group treatment program designed to address ER deficits in youth with ASD and/or DD. The intensive 5 week program utilizes cognitive behavior, applied behavior analysis, and mindfulness techniques and includes biweekly child and parent groups. Results indicate that this program is feasible and associated with high caregiver satisfaction. Pre-and-post outcome results indicate statistically significant improvement on behavioral measures, but did not demonstrate significant improv-ment on the Pediatric Quality of Life Family Impact Module. Based on overall positive outcomes, a randomized controlled trial of the program is indicated.

Keywords Autism Spectrum Disorder · Emotion regulation · Group treatment · Intensive outpatient programming · Cognitive behavioral therapy · Parent training

Individuals with Autism Spectrum Disorder (ASD) and/or other intellectual disability (ID) often struggle with behavior management and emotion regulation (ER), and treatment methodologies focusing on ER has become a topic of increasing interest in ASD and ID research. In 2004, Eisenberg defined ER as the ability to modulate experiences and expression of emotions in a socially acceptable manner that allows one to achieve personal goals (Eisenberg and Spinrad 2004; Campos et al. 2004). Mazefsky and White (2014) expanded on this concept by suggesting that ER is a method of controlling the intensity of one's emotion, at either a conscious or unconscious level, before or after a triggering event. Adaptive ER involves utilizing effective coping strategies to deal appropriately with challenging situations and

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emotions, whereas maladaptive ER is frequently associated with behavioral challenges and the development of psychopathology (Siener and Kerns 2012; Rieffe et al. 2011; Cisler et al. 2010). When children do not develop adaptive ER, they frequently experience difficulties in interpersonal relationships and academic performance (Hill et al. 2006). More specifically, individuals distracted by emotional outbursts may be less accepted by peers and may miss key learning opportunities in social and academic environments, ultimately exacerbating existing challenges in attention, problem-solving, communication, and social interaction (Samson et al. 2012).

Research exploring ER deficits in youth with ASD has demonstrated that these individuals can have difficulty recognizing their own and others emotions and therefore tend to engage in fewer adequate coping strategies compared to typical peers (Jahromi et al. 2012). This can lead to impaired communication of affect, which is an important component of adaptive ER (Mazefsky and White 2014). Jahromi et al. (2012) found impaired ER among children with ASD compared to typical peers and suggested this deficit may be related to impaired executive functioning, joint engagement, and effortful control (Jahromi et al. 2012). Conversely, children with ASD who demonstrate comparatively better

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control of their emotions have greater prosocial behavior, suggesting that strength in ER may be a protective factor for social skill development. ER deficits in youth with ASD have also been associated with serious behavioral disturbances including aggressive behavior and development of co-morbid behavior and psychiatric disorders (Mazefsky et al. 2012, 2013; Konstantareas and Stewart 2006). Therefore, treating ER deficits may have a positive impact on social skill development as well as irritability, anxiety, and mood symptoms in youth with ASD (Mazefsky and White 2014). Although the literature exploring ER deficits and treatment in the broader population of youth with ID is more sparse, these children are likely to have similar challenges with emotion recognition and regulation and to benefit from treatment strategies focused on development of adaptive ER (Mcclure et al. 2009).

Cognitive behavioral therapy (CBT) is a well-established treatment model that is partially effective for treatment of ER deficits in individuals with ASD (Sofronoff et al. 2005, 2007; Scarpa and Reyes 2011; Weiss et al. 2018). Sofronoff et al. (2005) examined ER after CBT intervention in 71 youth ages 10-12 with ASD and anxiety and 52 youth ages 10-14 with ASD and anger difficulties and found improved understanding of anxiety and anger management following 6 weeks of group CBT treatment (Sofronoff et al. 2005, 2007). Scarpa and Reyes (2011) adapted Sofronoff's curriculum for children ages 5-7 with a concurrent parent group and found decreased tantrums, shorter duration of tantrums, significantly more strategies on vignettes, and parents reported higher levels of confidence in managing anxiety. In addition, Weiss et al. (2018) created a CBT program to address multiple manifestations of ER, including anxiety, in children with ASD through a 10 week individual treatment program. Participants in the active treatment group demonstrated greater improvement than the waitlist control on measures of ER rated by parents, clinicians, and patients giving further evidence of the utility of CBT for ER deficits in ASD. However, CBT alone may not fully address maladaptive ER and associated behavior problems in youth with ASD/ID, as the default emotion regulatory approaches of these children may overwhelm attempts to cognitively implement newly learned skills and coping strategies (Aldao et al. 2010; Aldao and Nolen-Hoeksema 2013). This struggle between emotional experience and cognitive implementation of skills has been identified in other psychiatric and behavioral pathologies including attention deficit-hyperactivity disorder (ADHD), anxiety disorders, depression, and borderline personality disorder (Blackledge and Hayes 2001; Blake et al. 2017; Burckhardt et al. 2017; Cotton et al. 2016; Hesse et al. 2015; Noguchi et al. 2017; Schneider et al. 2016; Tarrasch et al. 2017; Vollestad et al. 2012). Research has demonstrated that this challenge can be effectively addressed via the use of mindfulness and acceptance based treatment interventions. These treatment methods focus on changing one's relationship with the identified problem, developing acceptance of thoughts, and behaving in a manner consistent with one's goals and values (Vollestad et al. 2012; Kumar et al. 2008). These strategies, while effective in treatment of many other disorders, have yet to be thoroughly examined as potential treatment of ER deficits in individuals with ASD/ ID.

In an effort to address the pressing need for efficient and effective treatment strategies for youth with ASD/ID and maladaptive ER, our group developed the Intensive Outpatient Program for Emotion Regulation Treatment (IO-PERT), a novel treatment program which incorporates CBT along with mindfulness treatment modalities. In this manuscript we provide a short description of the program and detail a retrospective chart review of initial program implementation. We hypothesized that IO-PERT could be implemented successfully in the target population, would be acceptable to families, and would achieve positive behavioral impact on participants. To this end we analyzed feasibility and satisfaction data, and took an initial look at our clinical outcome measures to determine if they were sufficiently sensitive to capture change in our treatment population.

Methods

IO-PERT Program Description

IO-PERT was developed for youth ages 8-12 years with identified ASD and/or ID, intellectual quotient (IQ) over 50, ER deficits and a wide range of co-occurring behavioral and psychiatric diagnoses (including ADHD, Anxiety and Mood disorders, and Intermittent Explosive Disorder). In order to meaningfully engage in the group dynamic, children were required to use complex speech (language abilities over age 4 years and use of sentences with at least two parts) based on parent report and clinician observation in the intake. Due to notable behavioral challenges arising in group educational and/or social environments in our target population, as well as the need for efficient and effective treatment, an intensive outpatient treatment model with sessions meeting twice per week for 5 weeks and including both child group treatment and caregiver group education modalities was chosen (Frankel et al. 2010; Laugeson et al. 2012; Reaven et al. 2012; Sofronoff et al. 2005, 2007; Wood et al. 2009).

Each IO-PERT session focuses on teaching participants new CBT and mindfulness skills and strengthening those skills via repeated practice both within group (where children could gain successful experience in a supportive environment) and as part of weekly homework. CBT techniques focusing on thoughts, feelings, and behaviors and the interaction between the three are incorporated throughout the curriculum (Olatunji et al. 2010; Yang et al. 2017). Resources such as CBT for anxiety and anger (Sofronoff et al. 2005, 2007), the Incredible 5-point scale (Buron and Curtis 2003), and Social Thinking (Kuypers 2011; Madrigal and Garcia Winner 2008) are employed along with new material written by the authors to specifically address ER. Additionally, fundamentals of mindfulness interventions are incorporated to directly address emotion dysregulation. Adapted versions of mindfulness exercises such as breathing meditation, body awareness and scanning, sound meditation, and focusing skills are taught and practiced during each session (de Bruin et al. 2015; Kumar et al. 2008; Segal et al. 2002). ABA techniques such as hierarchies of prompting, planned ignoring, guided compliance, and differential reinforcement, and behavior plans are consistently implemented throughout the curriculum (Granpeesheh et al. 2009; Lovaas et al. 1973; Virues-Ortega 2010). Table 1 outlines the material and rational for each child session. A decision was made to include a wide range of intellectual abilities based upon the need in the referral base. Despite limited evidence regarding the usefulness of CBT with intellectual disabilities, a strong evidence base exists for the ABA teaching strategies in ID, ASD, and developmental disabilities (DD) in general (Ali et al. 2015; Granpeesheh et al. 2009; Virues-Ortega 2010; Hwang and Kearney 2013; Mcclure et al. 2009; McGillivray and Kershaw 2015; Unwin et al. 2016). These strategies were used to teach the new material and skills at an appropriate age level but with use of additional practice, reinforcement, repetition, and visuals to help the children learn the material. Adaptations were made to teach it in more detail if group members were struggling to understand the material.

The IO-PERT caregiver training curriculum is structured similarly to the child group, with its foundations in CBT, ABA, and mindfulness principles. The caregiver group also provides direct instruction in ABA principles including understanding the functions of behavior, prevention strategies, reinforcement schedules, and appropriate use of consequences. All caregiver material was written by the authors but was based in ABA technique commonly included in caregiver training models (Sofronoff and Farbotko 2002; Shaffer and Minshawi 2014). The IO-PERT caregiver education group is felt to be of pivotal importance in the program, as evidence demonstrates that caregivers have a significant effect upon their child's treatment outcome and the durability of therapeutic change (Frankel et al. 2010; Laugeson et al. 2012, 2009; Mandelberg et al. 2014; Chang et al. 2014; Shaffer and Minshawi 2014; Bearss et al. 2015; Scahill et al. 2016). Table 1 outlines the material and rationale for each caregiver session.

Retrospective Chart Review

A chart review of all participants screened for IO-PERT between July 2015 and December 2016 was completed. Individuals who completed both intake and discharge measures and attended at least eight sessions were assigned a study ID number to maintain confidentiality and were included in the statistical analysis of outcome measures. The IO-PERT intake, weekly treatment, and discharge notes were the primary sources of clinical information utilized, from which demographic, outcome measure, behavior rating, and treatment goal progress data was gathered. Informed consent for this retrospective review was waived by our local IRB.

Demographic data including age, sex, race, intellectual functioning when available, and Clinical Global Impression-Severity Scale (CGI-S) clinician rating at IO-PERT intake appointment (Guy 1976) was collected. To evaluate feasibility, the number of screen failures, group completion rates, and attendance at each session was extracted from the charts. Acceptability was assessed through weekly Caregiver Satisfaction Surveys asking caregivers to rate how much they learned, how satisfied they were with the material, how confident they felt managing their child, and how well their child was applying the skills from the program. Answers are rated on a 6-point Likert scale ranging from 0 (not at all or nothing) to 5 (a great deal or very). Caregivers were also given the option to write comments at the bottom of the weekly surveys.

To evaluate initial outcome data, pre- and post-treatment clinical assessment measures were extracted. These measures included the caregiver reported Achenbach Child Behavior Checklist (CBCL) (Achenbach and Rescorla 2001), Aberrant Behavior Checklist-Community (ABC-C) (Aman and Singh 1986), the Pediatric Quality of Life-Family Impact Module (PedsQL) (Varni et al. 2004), and a total number of behavioral incidents reported by caregivers each week. Additionally, the lead clinician completed the Clinical Global Impression-Improvement Scale (CGI-I) (Guy 1976) and rated achievement of treatment goals in the chart at week 5.

Outcome Measures

The CBCL for children ages 6–18 years obtains caregiver ratings of 112 problem behaviors (Achenbach and Rescorla 2001). The CBCL assesses symptoms on the following subscales: Anxious/Depressed, Withdrawn/Depressed, Somatic Complaints, Social Problems, Thought Problems, Attention Problems, Rule-Breaking Behavior and Aggressive Behavior. In addition to a total problems score, six DSM-Oriented subscales are also assessed on the CBCL. The CBCL is a parent-completed rating scale of challenging behavior. It measures both internalizing

Caregiver group			Child group	
Topic and evidence based methods	Main activities within the overall structure	Purpose/rationale	Main activities within the overall structure	Purpose/rationale
Session 1: Introductions and emotion identification CBT Identification of Emotions (Sofronoff et al. 2005, 2007)	 Identification of child's problem behaviors Discussion of crisis management and safety planning 	 Establish rapport Foster understanding and preparation regarding emotion regulation 	 Create group rules and explanation of group structure Introductions to emotions with sorting task and bingo game 	 Establish rapport Provide structure for a positive group Education about Emotion Identification
Session 2: Functions of Behavior and Relaxation Parent Session: ABA methodology (Sofronoff and Farbotko 2002; Shaffer and Minshawi 2014) Child Session: Mindfulness relaxa- tion strategies and progressive muscle relaxation (Vollestad et al. 2012)	 Education on the four primary functions of behavior (attention, escape, tangible and sensory) Education about data collection Discussion of relaxation strategies Practice relaxation exercises of breathing and muscle relaxation 	 Lay groundwork for caregivers understanding the foundation of behavioral therapy Raise awareness to moments of calm with child and physical signs of relaxation Develop caregiver skills with relaxation strategies for in-home coaching 	 Participants identify what makes them relaxed Categorize situations into relaxed or not relaxed Complete worksheet to consider body signs of relaxation Practice relaxation exercises of breathing and muscle relaxation 	 Increase insight into relaxing activities Develop participants understanding of their body signals Learn effective relaxation strategies that can be used in a variety of settings
Session 3: Prevention Strategies and Triggers Parent Session: ABA methodol- ogy (Shaffer and Minshawi 2014; Bearss et al. 2015) Child Session: CBT understanding triggers and Mindfulness body awareness (Sofronoff et al. 2007; Vollestad et al. 2012)	 Complete anger checklist to iden- tify their child's triggers to anger Educate on prevention strategies (e.g. avoiding certain situations, controlling the environment) and when to use them 	 Increase caregiver understanding of the importance of knowing and understanding triggers to anger Develop caregiver confidence in preparing for potentially triggering situations 	 Complete anger checklist to identify their triggers Discuss what happens to their thoughts and bodies when angry Sorting game of body signs when feeling angry versus not feeing angry 	 Increase child knowledge and understanding of triggers to anger Develop insight into connection between angry feelings and behav- iors/outcomes
Session 4: Recognizing and Rating Anger Parent and Child: CBT rating of emotions (Sofronoff et al. 2007; Kuypers 2011)	 Introduction of the 5 point scale to rate emotions Refer back to trigger sheet to assign a rating to each Introduction of Problem Sizes (small, medium and large) from "The Zones of Regulation" and why our reactions to problems should fit the size that majority would perceive it to be 	 Provides caregivers with the language to discuss level of emotion with their child Develop caregiver ability to differentiate between their child's emotional reaction to a problem and how most people would view the problem 	 Introduction of the 5 point scale to rate emotions Participants engage in rating task to identify their emotion level Participants create a scale to take home Refer back to trigger sheet to assign a rating to each Complete drawing worksheets for ratings 1 and 2 	 Psychoeducation on how emotions escalate Develop participant understanding into face and body clues associated with emotions, labeling their own emotions at each level, and how they make others feel when at each level
Session 5: Responses to behaviors and problem sizes Parent: ABA use of reinforcements (Bearss et al. 2015; Shaffer and Minshawi 2014) Child: CBT ratings continued	 Discussion of effective responses to behaviors Introduction to types of reinforc- ers and appropriate utilization of reinforcers Educate on use of token econo- mies, reward systems, positive attention and planned ignoring protocol to respond to behaviors 	 Increase caregiver insight into the effectiveness of a positive based behavior system Develop behavior system for caregivers to implement in the home 	 Review 5-point ratings and practice with visual scale and cards Complete drawing worksheets for ratings 3, 4 and 5 ratings Education on Problem Sizes (small, medium and large) from "The Zones of Regulation"(Kuypers 2011) 	 Further psychoeducation on emo- tional levels Develop ability to differentiate between personal emotional reaction to a problem and how most people would view the problem

Table 1 Session overview

498

Caregiver group			Child group	
Topic and evidence based methods	Main activities within the overall structure	Purpose/rationale	Main activities within the overall structure	Purpose/rationale
Session 6: Problem Solving Parent and Child: CBT and Mindful- ness/acceptance methodology (Vollestad et al. 2012; Sofronoff et al. 2007)	 Introduce Problem Solving Model Participants brainstorm possible solutions to go in each choice bubble and process outcomes of each choice Discussion of which choices they feel their children carry out well and how to coach on them on the other positive choices 	 Identify that there are more possible positive problem solving solutions than negative Increase caregiver ability to coach child on utilization of positive problem solving strategies 	 Introduce Problem Solving Model Participants brainstorm possible solutions to go in each choice bubble and process outcomes of each choice Complete their own Problem Solv- ing Model to take home Conduct role plays exemplifying use 	 Identify that there are more possible positive problem solving solutions than negative Increase participants ability to think through problems and implement positive problem solving strategies
Session 7: Thoughts and Anger Parent and Child: CBT (Sofronoff et al. 2005, 2007)	 Introduce positive versus negative thinking with worksheet Process how adults often have to challenge negative thoughts in themselves as well as with their children 	• Educate how thoughts are connect to actions and then to consequences, identifying specific examples for each child	 Introduce positive versus negative thinking and educate how thoughts are connected to actions and then to consequences Participants practice identifying positive and negative thoughts 	 Educate how thoughts are connect to actions and then to consequences Practice with thought identification
Session 8: Thoughts Continued Parent and Child: CBT and Mind- fulness (Vollestad et al. 2012; Sofronoff et al. 2005)	 Introduce Inner Critic and Inner Coach from "The Zones of Regu- lation" (Kuypers 2011) Educate on tools Inner Coach can use for positive thinking such as, reality checks, consequential think- ing and positive imagery Teach and practice mindfulness with a piece of candy using all five senses 	 Create a more concrete approach to positive and negative thinking AID variety of ways to implement thinking tools 	 Introduce Inner Critic and Inner Coach from the Zones of Regula- tion and complete worksheet Teach and practice mindfulness with a piece of candy using all five senses 	 Educate on tools Inner Coach can use for positive thinking such as, reality checks, consequential think- ing and positive imagery Practice skills to increase ability to apply outside of group setting
Session 9: Friendships Parent and Child: CBT and ABA methods (Granpeesheh et al. 2009; Wood et al. 2009)	 Introduction of social skills and how others can be helpful when upset Discussion of how to help children connect to appropriate social groups and identify potential com- munity groups for children to join 	 Educate on choosing appropriate friends and how they can support us in times of needs Provide caregivers with list of social possibilities and gather ideas from group members to pro- mote future friendship building 	 Introduction of social skills and how others can be helpful when upset Participants complete the Circles of Support worksheet to reinforce who provides them with social support Teach conversation skills 	 Increase participant insight into characteristics of a good friendship and potential social groups to meet friends Provide basic conversation skills for practice outside of group

Table 1 (continued)

499

Caregiver group			Child group	
Topic and evidence based methods Main activities within the overall structure	Main activities within the overall structure	Purpose/rationale	Main activities within the overall structure	Purpose/rationale
Session 10: Review and Graduation	 Review program topics and how to implement information post-group Complete discharge assessments and satisfaction surveys Provide any needed information for ongoing resources and thera- peutic support Graduation ceremony with chil- dren 	 Review program topics and how to information post-group implement information post-group implement information post-group condities assessments and satisfaction surveys Complete discharge assessments and satisfaction surveys Complete discharge assessments coaching skills post-group and satisfaction surveys Gather discharge data for comparination for ongoing resources and thera- provide any needed information for ongoing resources and thera- previders if needed Graduation ceremony with chil- Resonance in group 	 Review of program topics Create Emotion Regulation Box with pocket-size versions of con- cepts covered through group Graduation ceremony with car- egivers including children demon- stration of skills and presentation of certificates 	 Reinforce group skills Provide easily accessible place for tool reminders to implement postgroup Recognize participant areas of excellence in group

Table 1 (continued)

and externalizing symptoms. The CBCL was empiricallyderived via factor analysis, but it also includes DSMoriented subscales. Internal consistency and 1-week test-retest reliability ranges from good to excellent for each of the domains with typically developing children (Achenbach and Rescorla 2001). Items are rated on a 3-point scale from (0) not true to (2) very true. The CBCL provides measurement of both internalizing and externalizing behaviors including anxiety, depression, and behavior difficulties, all of which have been indicated as related to ER.

The ABC-C is a 58-item caregiver report questionnaire on behavior difficulties commonly seen in individuals with DD (Aman and Singh 1986). There are five subscales derived by factor analysis: Irritability, Social Withdrawal/Lethargy, Stereotypy, Hyperactivity, and Inappropriate Speech. The ABC has been extensively used in psychopharmacological studies of ASD other DD (Aman et al. 2009). Caregivers rate the severity of behaviors (i.e. temper tantrums/outbursts) on a 4-point scale ranging from 'not a problem' (0) to 'the problem is severe in degree' (3). The ABC has been used previously as an indicator of irritability and behavioral impairment, two closely related indicators of ER impairment in ASD.

Quality of life was assessed with the PedsQL, measuring the impact of child chronic health conditions on caregiver physical, emotional, social, and cognitive functioning, communication, and worry (Varni et al. 2004). This scale also measures caregiver reported family functioning in the form of daily activities and relationships. Internal consistently is excellent and it has been used across many pediatric disorders (Medrano et al. 2013; Varni et al. 2004). This scale is rated on a 5-point scale ranging from 'never' (0) to 'almost always' (4). The measure provides core scores of Parent Health-Related Quality of Life, Family Functioning, and Total Score. Although not directly related to ER, this measure was used as a possible indicator of any positive impact on the family.

The CGI-I was utilized as a clinician-rated dichotomous outcome measure to assess response to treatment. A trained clinician rated the improvement (CGI-I) at completion of IO-PERT (Guy 1976). CGI-I has been used extensively in ASD pharmacology and behavioral trials (King et al. 2009; McDougle et al. 2005; Bearss et al. 2015; Minshawi et al. 2016). The CGI-I provides a qualitative measure of treatment response through a rating from 1 to 7 (1 = very much improved; 2 = much improved; 3 = minimally improved; 4 = no change; 5 = minimally worse; 6 = much worse; 7 = very much worse). Rater training was conducted with gold standard vignettes and inter-rater reliability of 80% or greater was established. At the end of treatment, subjects with a CGI-I of "1" or "2" were categorized as responding to the treatment and subjects with CGI-I scores of "3" or higher were categorized as "nonresponders."

Statistical Analysis

To test the effects of the intervention a series of repeated measures ANOVAs were conducted by testing the within subjects factor of time (i.e. pre- vs. post) on each of the outcome measures. Next, a series of repeated measures ANCOVAs were conducted to test the same effects of the intervention for each of the outcomes while accounting for the effects of the three individual characteristics. Specifically, the effects of the within-subjects factor of time was tested for each outcome while covarying the effects of sex, age, and ASD status. Age was dichotomized using a median split (median = 10) with 19 participants in the younger group (i.e. 8, 9, and 10 year olds) and 15 in the older group (i.e. 11 and 12 year olds). Finally, each of the three individual characteristics and four intervention rating measures (i.e. learn, confidence, and apply) were tested as moderators of the effects of the intervention. Satisfaction was not tested as a moderator because there was no variability in this measure (i.e. all participants rated that they were satisfied). For the purposes of the analyses, each of the items were dichotomized. Specifically, scores of 0-3 (i.e. negative to neutral ratings) were scored as 0 and scores of 4 and 5 (i.e. positive ratings) were scored as 1. Specifically, a series of repeated measures ANOVAs tested the interaction between the within-subjects factor of time and one of each of the six possible moderators for each of the outcome measures.

Results

Participants

51 individuals were screened and 40 participants were enrolled in IO-PERT between June 2015 and December 2016 (six rounds of IO-PERT groups). Six participants left the program without completing (see detail below). Completing participants included 26 males and 8 females between the ages of 8 and 12 (M = 10.17, SD = 1.48). Participants were predominantly Caucasian (91.2%), 8.8% African American, and one participant who did not report race. Primary diagnosis of participants was reported by caregivers and confirmed via chart review when possible. Primary diagnoses included ASD (n=20, 58.8%), Attention Deficit Hyperactivity Disorder (n = 11, 32.4%), and Generalized Anxiety Disorder (n = 3, 8.8%). Twenty-three participants additionally had a secondary diagnosis (ADHD, Generalized Anxiety Disorder, Anxiety Disorder Unspecified, Disruptive Behavior Disorder, Oppositional Defiant Disorder, and Intermittent Explosive Disorder) and 8 had a third diagnosis (Anxiety, Intermittent Explosive Disorder, Depressive Disorder, and Disruptive Mood Dysregulation Disorder). Reasons for referrals included irritability, mood swings, tantrums, aggression (both physical and verbal), noncompliance, easily triggered to anger, anxiety, lack of understanding of emotions, rigidity leading to tantrums/outbursts, and difficulty calming down when upset. Emotion regulation was specifically discussed in the intake and families confirmed that their children struggled in this area. CGI-S scores at intake included ratings of 3 (n=8, 23.5%), 4 (n=21, 61.8%), and 5 (n=5, 14.7%). Intellectual functioning of participants was not screened formally for participation in IO-PERT, however chart review of completing participants reveals a mean full scale IQ of 90.4, SD = 18.29 (n = 25), verbal IQ of 92.46, SD = 19.72 (n = 24), and nonverbal IQ of 93.59, SD = 18.97(n=24). Full scale IQ scores ranged from 56 to 132.

Feasibility

Fifty-one intakes were completed during the defined period, with 11 participants (22%) determined to be inappropriate for IO-PERT at intake due to behavior judged to be too severe for a group setting (n=2), behavior too mild for intensity of program (n=1), schedule conflicts (n=5), transportation difficulties (n = 1), and incompatible insurance (n=2). Of the 40 children who started IO-PERT, 6 did not complete the program. Four children were lost to follow-up without explanation, one child had an incompatible change in insurance, and one child was asked to discontinue due to severity of disruptive behavior (patient was subsequently treated individually and later able to complete IO-PERT in a different round). Of the 34 children who completed the program, there was a 13% absence rate across the six rounds indicating that each family missed 1.3 sessions on average. Families reported a variety of reasons for missed sessions including weather, illness, school events, and work commitments.

Acceptability

Feedback was obtained via the Caregiver Satisfaction Survey at the end of each week to determine how satisfied families were with the material. General satisfaction with the program was consistent across the 5 weeks with the highest percentage of caregivers reporting feeling "highly satisfied" with the program in week-2 and week-5. Caregivers reported learning the most during week-4 of the program (44% "learned a great deal"). From pre- to post-treatment, caregivers reported an increase in confidence managing their child's behaviors from 50% feeling "somewhat confident" at week-1 to 66.7% feeling "confident" at week-5.

At end of treatment, 100% of caregivers reported being "highly satisfied" or "satisfied" with the treatment program.

Additionally, 84.4% of caregivers reported learning "a great deal" or a "moderate amount," with only 15.2% reporting that they learned "some new things." Caregivers reported that 6.3% of their children were using skills taught in IO-PERT "very well," 37.5% were using skills "moderately" well, 46.9% were "somewhat using skills," 6.3% reported "minimal use of skills," and 3.1% reported "no application" of skills.

On the Caregiver Satisfaction Survey, the caregiver provided comments were rated by two IOP staff as positive or negative. If they were not clearly one of the two they were excluded. Caregivers provided 117 unprompted positive comments over the course of the program. Positive comments ranged from noted changes in child's behavior, use of skills, family environment, gratefulness for assistance, and appreciation for other parents sharing their experiences. Caregivers provided only 16 concerning/negative comments ranging from concerns about clinician management of caregiver participants who monopolized the sessions to the course material being too basic for their specific child.

Outcome Measures

Of the 34 children who completed the program, caregiver completed discharge measures were available at the following rates: 32 for the ABC (94%), 31 for the CBCL (91%), and 29 for the PedsQL Family Impact Module (85%). Reasons for lack of discharge measures included families being absent from the last session or the caregiver who completed intake paperwork not being present. The PedsQL was not added to the outcome measures until the second round of the program. Clinician rated CGI-I and achievement of treatment goals were available for all 34 children who completed the program.

The effects of the intervention were tested with a series of repeated measures ANOVAs which tested the difference in each outcome measure at pre- and post-intervention time points. As seen in Table 2, there were significant decreases from pre- to post-time points for the following 11 outcome measures: anxious/depressed, somatic complaints, thought problems, attention problems, rule-breaking behavior, aggressive behavior, irritability, lethargy/social withdrawal, stereotypy, hyperactivity, and inappropriate speech. Next, the same effects of the intervention were tested while accounting for individual characteristics. Specifically, a series of repeated measures ANCOVAs tested the difference in each outcome measure at pre- and post-intervention time points while covarying the effects of sex, age, and ASD status from the intervention effects. As seen in Table 2, the following nine outcome measures had significant effects of time after controlling for the three individual characteristics: anxious/depressed, social problems, thought problems, rulebreaking behavior, aggressive behavior, irritability, lethargy/ social withdrawal, and inappropriate speech. Specifically, the ratings in each of these areas improved over time from intake to discharge. Comparing the analyses with no covariates versus those with the covariates of sex, age, and ASD status, somatic complaints, attention problems, stereotypy, and hyperactivity were no longer significant after the control measures were entered and social problems became significant once the control measures were entered. An examination of the covariate effects in the analyses suggest that accounting for the effects of gender was what led to the significant effects to appear in the second set of analyses for social problems. When gender was controlled, social skills became a significant area of improvement.

Next, we tested if the effects of the intervention were moderated by any of the individual characteristics (i.e. sex, age, gender) or three parent survey rating of their learning, parent confidence in managing behaviors, and their child's application of skills by testing the interactions between each of these possible moderators and time (i.e. pre vs. post) for each outcome measures. The three individual characteristics were not found to significantly moderate the effects of time (all F-values < 3.12, p > .08). For the intervention rating measures, learn and apply did not moderate the effects of time (all F-values < 2.98, p > .10) but confidence was a significant moderator of time for thought problems (F (1,25) = 11.54, p < .003; $\eta^2 = 0.32$), attention (F (1,25) = 5.00, p < .04; $\eta^2 = 0.17$), irritability (F (1,26) = 5.72, p < .03; $\eta^2 = 0.18$), lethargy (F (1,26) = 7.64, $p < .02; \eta^2 = 0.23$), and hyperactivity (F (1,26) = 9.06, p < .007; $\eta^2 = 0.26$). See Fig. 1 for graphic representations of the follow-up analyses. At low levels of confidence, there were no significant difference in the five outcome measures from pre- to post-time points (all *t*-values < 1.01, all ps > .35) but at high levels of confidence each of the outcome measures had significant decreases from pre- to post-time points (all *t*-values > 3.41, all *ps* < .003). Specifically, parents who rated higher levels of confidence in managing their child were more likely to also report improvements for their child in thought problems, attention, lethargy, irritability, and hyperactivity.

On the clinician-rated CGI-I, 18 out of 34 participants (53%) were deemed clinical responders with a rating of "much improved" at the end of study. Eight participants (24%) were judged to be "minimally improved," while seven participants (21%) were felt to have "no change" over the course of treatment. One participant had worsening behavior at the end of the study, with a final CGI-I rating of "minimally worse." No participants were felt to be "much worse," or "very much worse" at the end of treatment. Mean CGI-I score at treatment completion was 2.7 (SD=0.89) which falls between "minimally improved" and "much improved."

Of the 34 children who completed the program, 26 (76.5%) achieved their pre-set treatment goals, 6 (17.6%)

	Pre M (SD)	Post M (SD)	No controls F-value	No controls I_1^2	Controls <i>F</i> -value	Controls η_p^2
CBCL		(-1		-1p
Anxious/depressed	67.03 (9.3)	63.74 (9.4)	7.26*	0.20	5.53*	0.17
Withdrawn	64.65 (10.8)	63.26 (11.1)	0.65	0.20	1.39	0.17
	. ,					
Somatic complaints	61.48 (9.6)	58.68 (9.0)	6.43*	0.18	1.66	0.06
Social problems	66.33 (9.6)	65.30 (9.8)	0.98	0.03	6.63*	0.20
Thought problems	71.19 (7.5)	67.71 (9.2)	8.01**	0.21	8.14**	0.23
Attention problems	67.71 (9.5)	63.68 (9.2)	9.12**	0.23	3.13	0.10
Rule-breaking behavior	61.39 (6.9)	59.52 (7.6)	4.38*	0.13	3.92*	0.12
Aggressive behavior	67.52 (10.6)	63.71 (11.2)	13.36***	0.31	13.12***	0.33
ABC						
Irritability	17.41 (9.9)	12.69 (10.9)	14.94***	0.33	3.86*	0.12
Lethargy/social withdrawal	10.31 (7.8)	7.28 (8.1)	7.39*	0.19	3.81*	0.11
Stereotypy	5.34 (4.7)	4.13 (4.4)	8.03**	0.21	2.01	0.07
Hyperactivity	17.53 (9.2)	13.59 (9.0)	9.45**	0.23	1.55	0.05
Inappropriate speech	3.69 (2.9)	2.88 (2.4)	6.76*	0.18	5.56*	0.17
PedsQL family impact						
Parent health-related QL	65.63 (18.1)	67.08 (21.5)	0.59	0.02	0.75	0.03
Family functioning	55.71 (24.5)	56.57 (24.1)	0.05	0.00	0.53	0.02
Total score	60.16 (17.9)	61.48 (21.2)	0.38	0.01	1.87	0.07

Table 2 Results from repeated measures ANOVAs and ANCOVAs testing differences between pre- and post-time points for each outcome measure not controlling and controlling for individual characteristics

F-values and η^2 are reported for repeated measures ANOVA and ANCOVA analyses both controlling for age, gender, and ASD status and not controlling for these measures

p < .05; **p < .01; ***p < .001

partially achieved, and 2 (5.9%) did not achieve their goals. Caregivers reported a mean of 9.15 (SD = 19.54) behavioral incidents at week-1 and a mean of 3.04 (SD = 4.44) incidents at week-5. Despite a decrease in problematic behaviors, this difference did not reach statistical significance [t(25) = 1.74, p = .09].

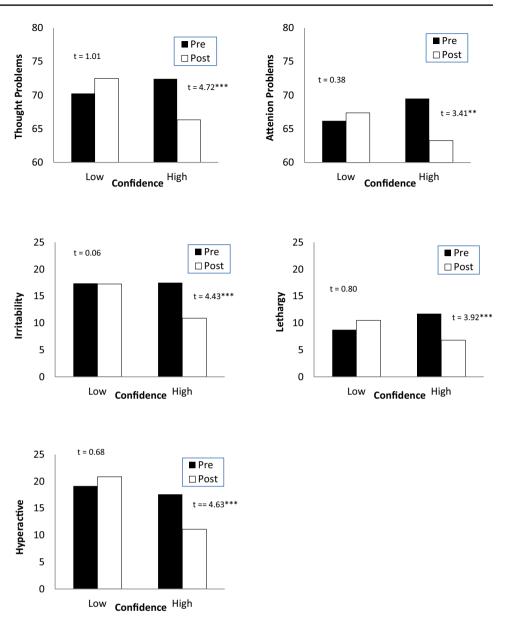
Discussion

This paper adds to a growing body of research on treatment of ER deficits in children with ASD and ID by outlining a novel model for teaching ER skills in an outpatient group-treatment setting. IO-PERT is firmly rooted in empirically supported CBT, ABA, and mindfulness techniques (Sofronoff et al. 2007; Granpeesheh et al. 2009; de Bruin et al. 2015), yet is novel in both its structure and approach. The group structure is an efficient and effective method of treating many youth with ASD/ID and ER deficits, while providing natural social interaction experiences within the therapeutic setting. The inclusion of caregiver training as part of IO-PERT is an innovative approach often overlooked in other group therapy interventions. IO-PERT caregiver training offers concrete strategies for managing challenging behaviors. Furthermore it creates an opportunity for caregivers to support and learn from each other. Our retrospective chart review of the initial 40 children who participated in IO-PERT provides additional insight into the feasibility and acceptability of the IO-PERT program, and an initial examination of the efficacy of the program and appropriateness of our selected outcome measures.

Feasibility results for this program are promising with 80% of the children who began the program reaching completion. Reasons for lack of completion ranged from severity of disruptive behavior, insurance changes, and no explanation from families. Children who did complete the program had acceptable attendance (13% absence rate).

Results suggest that caregivers were very accepting of the IO-PERT program, with 100% of responders indicating that they were "satisfied" or "highly satisfied" at program conclusion. Caregiver "buy-in" can impact treatment adherence, particularly for time intensive programs such as this one, so this response is highly clinically significant. Additionally, most caregivers indicated that they learned new concepts and strategies and were "confident" in their ability to manage their child's behavior at conclusion of the program. Furthermore, 88% of unprompted caregiver comments about the program were positive. Despite these positive responses, caregiver reports of skill implementation on the part of youth

Fig. 1 Bar graphs depicting the follow-up findings with the means for outcome measures with significant time by confidence interactions. *p < .05, **p < .01, ***p < .001; Followup analyses found that at high levels of confidence there were significant decreases in the all five outcome measures from pre to post (all t values > 3.41. ps < .003). For those low in confidence there were no significant changes in each of the five outcomes from pre to post (all t-values < 1.01, ps > .35)



enrolled in the program was lower than we had hoped, which is an area for further exploration and work by our group.

Though the goal of this initial work was to assess feasibility and acceptability of IO-PERT design and content, an initial examination of the efficacy of the program and appropriateness of the chosen outcome measures is imperative as we consider future IO-PERT clinical research. Overall IO-PERT appears to have a positive impact on participating youth, which was adequately captured by the CBCL, ABC-C, and CGI-I. When individual characteristics of age, gender, and ASD diagnosis were controlled, caregivers reported improvements in anxiety, social problems, thought problems, rule breaking behavior, aggressive behavior, irritability, lethargy/social withdrawal, and inappropriate speech. These results are promising and the changes suggest that IO-PERT was effective in teaching coping skills. Additionally, social skill improvement suggests the secondary goal of increasing appropriate social interactions in the group was effective. Clinician rated CGI-I scores indicate that 47.2% of the participants had clinically meaningful change with this treatment. Additionally, caregivers reported a decrease in number of behavioral incidents outside of group over the course of the program.

Of particular note is that high parent confidence in managing their child's behavior at the end of the group appeared to increase the effectiveness of the intervention on the child's behavior changes on outcome measures. It is not surprising that higher parental confidence enhanced the effects of the project, given the critical role parents play in the current intervention and strong evidence in the general child and parenting literature that self-efficacy/confidence around of managing difficult behaviors is an important factor to consider in regard to reducing child behavior difficulties (Hastings and Brown 2002; Stoneman and Crapps 1988; Gowen et al. 1989). Bandura's conceptualization of self-efficacy as a perception of one's own skills in a given domain has been found to play an important role in the relationship between a range of outcomes including parenting stress and behaviors (Bandura 1989). Parental self-efficacy is related to various outcomes including parenting behavior and stress (Coleman and Karraker 1998). Conversely, child behavior problems and caregiver burden has also been predictive of a parents' self-efficacy. Parental self-efficacy has been examined extensively as an outcome measure and as a predictor of parental outcomes but is less understood in regard to predictive function of child behavior (Hastings and Brown 2002). It is possible that the education paired with the support of other parent group members led to high confidence in managing their children which then led to better implementation of behavioral strategies outside of group with their children and ultimately better behavior. Another explanation is a more symbiotic relationship in which child improved behavior through group skills increased parental confidence which then also led to even more improved behavior. Future studies could further evaluate the relationship between parental confidence and child behavior.

Unfortunately, despite improvements in behavior and high acceptability ratings by caregivers, no significant change was detected on the PedsQL following IO-PERT treatment. This outcome measure may have not detected change in this cohort due to its intended design as an assessment for families of children with health-related difficulties. It is also possible that the brief intervention period (5 weeks) was not sufficient to adequately measure change in our treatment population. Future evaluations of this treatment model may need to explore a new outcome measure regarding treatment impact to the family. It will also be helpful to have a longer follow up period to assess long term change.

Limitations

The results of this work must be considered within the context of its limitations. As the focus of this was program development, feasibility, and acceptability, we did not include a control group to examine efficacy in a meaningful way. In the future, this program should be explored in a more standardized manner with the inclusion of a wait-list control or treatment-as-usual control group. This short-term nature of the treatment may also be an important limitation. Though the reduced time demand likely increased accessibility and acceptability of the program for families, 5 weeks may be too brief of a period in which to measure meaningful change, particularly in family

functioning. Long-term outcome data (i.e. follow-up at 5, 10, or 15 weeks post-treatment) is needed to further assess durability and/or continued improvement post-treatment. Anecdotally, many families have reached out to the treatment team to report continued change months after treatment concluded, capturing this ongoing improvement on objective measures is a goal of future research.

Another limitation of this study is the lack of an ER specific measure. At the time of the program creation, an ER measure was not validated in the ASD population. Mazefsky et al. (2018) has since created and validated a measure of ER change in a broad range of functioning and it has been implemented as an outcome measure in IO-PERT. It is an efficient and easily administered measure for parents and allows assessment of change in a short time period. Future studies of IO-PERT will utilize this measure.

Future Directions and Conclusion

This examination of IO-PERT, a novel group therapy treatment targeting ER in youth with ASD/DD, provides promising initial results in feasibility, acceptability, and efficacy. Caregivers expressed a high level of satisfaction with the program, and pre- and post-results on the majority of the objective outcome measures indicated improvements in behavioral functioning of participants. Future work is needed to examine the true efficacy of this program with a randomized control trial utilizing either a treatment-as-usual group or a waitlist-control group. Furthermore, measure of long-term outcomes is an important area of future exploration. Finally, coupling this treatment with pharmacologic intervention may be a novel approach to enhancing efficacy of this type of treatment intervention (Wink et al. 2017).

In conclusion, the unique model of this program including the group atmosphere, caregiver training component, and its short duration and intensive nature holds great promise. Families of children with ASD/ID are often stressed and have limited resources and time. This model holds potential to improve patient access time limited, multi-modal treatment to jump start meaningful behavior change.

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program implementation, MS supported the program implementation, CAE assisted with program development and manuscript development.

Compliance with Ethical Standards

Conflict of interest All authors declare declare that they have no conflict of interest.

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