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STUDY PROTOCOL

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Study protocol for a randomized controlled trial of Regulating Together (RT), a group therapy for emotion dysregulation in school-age autistic youth and their caregivers

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Abstract

Background Emotion dysregulation is a common concern in autistic youth. Growing evidence suggests emotion dysregulation underlies multiple co-occurring issues in autism, including externalizing (e.g., aggression, irritability) and internalizing (e.g., anxiety, depression) disorders, and thus may serve as a key transdiagnostic treatment target. Emotion dysregulation during middle childhood (8–12 years) is concurrently and longitudinally associated with social difficulties and poorer quality of life for autistic individuals, highlighting a key window for intervention. There is an urgent need for treatments for emotion dysregulation in school-age autistic youth that involve caregivers to maximize skill generalization. To address this need, our group developed *Regulating Together*, an intensive outpatient group program targeting emotion dysregulation in 8- to 12-year-old autistic youth that integrates strategies from cognitive behavioral therapy, mindfulness and acceptance-based therapies, and parent training programs. Building on our previous non-randomized trials of *Regulating Together*, we document the study protocol for our first, and ongoing, randomized controlled trial comparing *Regulating Together* to an active control condition.

Methods This is a five-year randomized controlled trial comparing *Regulating Together* to Achieving Independence and Mastery in School (AIMS), an active control condition targeting executive functioning difficulties, in an outpatient hospital setting. Enrollment is ongoing and the study is expected to be completed in late Fall of 2026. Participants will be 144 autistic youth (8–12 years; IQ ≥ 65) randomized to either 5-week treatment condition. A comprehensive assessment battery integrating self-, caregiver-, and clinician-report information, functional outcomes (i.e., number of psychiatric hospitalizations), objective outcomes (probabilistic reversal learning task), and biobehavioral measures (heart rate variability) will be collected and compared between baseline (Week 0), post-treatment (Week 7), post-generalization (Week 16), and at long-term follow-up (Week 29).

Discussion This is the first comparison of the *Regulating Together* program to an active treatment condition. Findings from this study will build on previous piloted iterations of *Regulating Together* by characterizing its efficacy in relation

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to active treatment, testing moderators of treatment response, and identifying barriers and facilitators to treatment access, impact, and sustainability. Following completion of this study, we will pursue implementation studies (e.g., testing program implementation and effectiveness in community settings). Dissemination and external provider training efforts are ongoing.

Trial registration Trial registration took place through ClinicalTrials.gov (NCT05803369) on March 14th, 2023.

Keywords Regulating together, Emotion dysregulation, Autism spectrum disorder, Cognitive behavioral therapy, Parent training, Mindfulness, Muscle relaxation, Neurodevelopmental disorders, Emotion regulation, Irritability

Background

Emotion dysregulation (ED) refers to difficulties modulating the experience, expression, and intensity of emotions in an adaptable and contextually appropriate manner [1]. ED often clinically manifests as anxiety, depression, aggression, self-injury, temper tantrums, and irritability [2–7].

ED is a significant concern for youth with autism spectrum disorder (ASD; hereafter "autistic youth"); over 80% of autistic youth experience co-occurring irritability [8], over 40% meet criteria for anxiety disorders [9, 10], over 45% have co-occurring attention-deficit/hyperactivity disorder [11], and as many as 70% are diagnosed with a mood disorder [10, 12–14]. ED challenges have been concurrently linked to higher rates of hospitalizations, suicidal ideation, school disciplinary action, peer rejection, poor postsecondary transitions, co-occurring psychiatric diagnoses, and use of psychotropic medications in autistic youth compared to their peers without ED [2, 7, 15–19]. Further, the presence of ED in autistic youth at 12 years of age predicts ED challenges that persist into young adulthood [20], including increased loneliness, increased social difficulties, and lower quality of life [21, 22]. Longitudinal studies suggest that treating ED before adolescence may reduce or prevent the likelihood of developing additional psychiatric diagnoses, self-harm behaviors, and psychiatric hospitalizations [23–25]. Thus, addressing ED before 12 years of age may be particularly effective in improving childhood and future adult outcomes across multiple settings.

Recent research has focused on transdiagnostic processes that may underlie numerous disorders, with ED being frequently identified as one shared underlying mechanism [26]. Consistent with this framework, internalizing and externalizing symptoms are both linked to underlying ED difficulties [27, 28] and often overlap in both autistic [26, 29] and typically developing youth [30, 31]. Thus, treatment may be more efficient, effective, and sustainable if underlying ED difficulties are treated rather than focusing on individual single diagnoses in a stepwise fashion [32, 33]. Despite the conceptual strength of this approach, most interventions developed for ASD have conceptualized anxiety and depression as distinct constructs [34–38]. Additionally, although anxiety treatments have proven effective for many autistic youth, these treatments rarely address more complex clinical presentations, such as autistic youth experiencing anxiety and co-occurring irritability, reactivity, and/or sadness [39]. This suggests that a treatment focused on select issues, such as anxiety or depression, may not comprehensively address concerns stemming from ED in ASD. Thus, an approach focused on underlying ED ultimately may be most beneficial for autistic youth experiencing ED.

Consistent with this approach, treatment focused on ED as an underlying mechanism in typically developing youth has driven widespread improvements in anxiety, depression, and caregiver-reported ED [40–44]. ED treatments also have been successfully utilized for youth with eating disorders [45], separation anxiety [44], depression [46], irritability [47], generalized anxiety [48], and borderline personality disorder [49]. Despite the availability of interventions targeting ED in youth with other disorders, these interventions are not tailored to the unique challenges faced by autistic youth experiencing ED such as communication differences (e.g., reduced receptive and expressive language), cognitive differences (e.g., co-occurring intellectual disability, cognitive inflexibility), and behavioral rigidity. Limited treatment options for ED in ASD are further exacerbated by a lack of provider experience in treating ASD or in treating ED within the context of ASD [50].

Within the field of ASD intervention, ED-focused research is still in its early stages. Currently, there is one manualized ED intervention for adolescents and young adults (EASE, individual therapy) [51], one for young children (STAMP, group based) [52], and one for school age youth (SAS: OR, individual) [53]. Although these programs have shown a positive impact on ED, EASE and SAS: OR are individual therapy treatment methods and STAMP only serves younger children (Table 1). Group interventions offer many benefits including efficiency (i.e., treatment of more than one child at the same time) and cost-effectiveness, normalization of ED difficulties for youth and families, and increased "buy-in" and motivation for youth and caregivers [54]. The inclusion of caregivers also is a valuable component for ASD

Table 1 Current interventions for ED in ASD

Intervention	Characteristics
Emotional Awareness and Skills Enhancement (EASE) [51] and EASE-Teams [57]	7–25 years; individual therapy; NVIQ > 50
Stress and Anger Management Plan (STAMP) [52]	4–7 years; group therapy; IQ > 70
Secret Agent Society: Operation Regulation (SAS: OR) [53]	8–12 years; individual therapy; no co-occurring intellectual disability

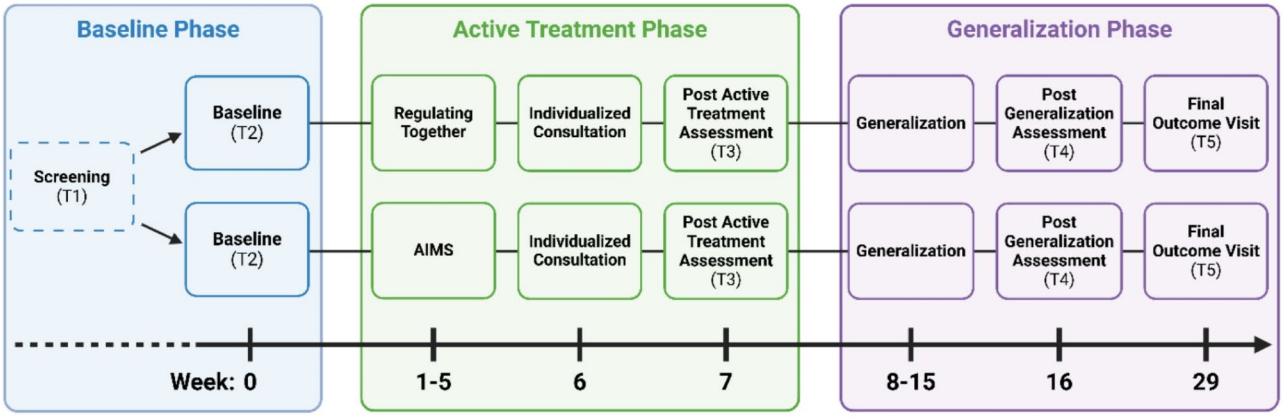

Fig. 1 Study timeline

interventions due to challenges with generalization of learned skills in autistic youth [55, 56].

To address the critical need for efficient, effective, and scalable intervention strategies for school-aged autistic youth experiencing ED, our group has developed the *Regulating Together* (RT) curriculum, an intensive outpatient group program targeting ED in 8- to 12-year-old autistic youth with IQ ≥ 65 [58, 59]. This program engages both caregivers and children and utilizes evidence-based intervention techniques including cognitive behavioral therapy (CBT), visual materials, reinforcement systems, scaffolding, and newer interventions such as mindfulness and acceptance-based therapy [60]. The program meets twice weekly for five weeks with concurrent child and caregiver groups followed by one final individualized consultation appointment after the last session. The active treatment phase is followed by a generalization phase (10 weeks) during which parents and youth practice the skills learned in RT. Evaluation of RT via retrospective chart review and an uncontrolled pilot trial has demonstrated initial efficacy, feasibility, and acceptability of the intervention [58, 59]. Our pilot studies demonstrated the importance of the generalization phase, as larger treatment effects were observed 10 weeks after treatment completion relative to immediately post-treatment. In terms of longer-term outcomes, a large reduction in hospitalization rate was found 12 months post-intervention compared to pre-intervention.

Here, we document the protocol for a randomized controlled trial (RCT) that incorporates an active control condition (ACC) for the first time in our RT development process. Given disparities in access to specialized autism services for many marginalized communities (e.g., racially and ethnically minoritized youth, youth from low SES backgrounds) [61], the protocol also incorporates qualitative interviews with all families to identify barriers to treatment feasibility and efficacy (e.g., childcare, transportation) to be addressed in future implementation trials.

Methods and design

Study aims

The primary study aims for this actively recruiting RCT are to: (1) Evaluate the short-term and long-term efficacy of RT compared to an ACC on ED; (2) Evaluate the efficacy of RT compared to an ACC on long-term functional outcomes (frequency and intensity of emotional outbursts and frequency of psychiatric hospitalizations) related to ED; and (3) Among non-diverse and diverse participants, explore facilitators and barriers to treatment response and participation to guide future implementation and dissemination research.

Study design

This is a five-year RCT that includes an experimental treatment condition (RT, Protocol Version 9.0, Finalized January 22nd, 2025) and an ACC (Fig. 1). Our ACC is Achieving Independence and Mastery in School (AIMS), a group therapy for autistic youth experiencing executive functioning difficulties that interfere with academic success [62]. Participant enrollment is ongoing, with the final group expected to enroll in the Spring of 2026 and the final outcome visit expected to be completed in the Fall of 2026.

Screening During the Screening visit (T1), potential participants will participate in a 2-and-a-half hour visit to establish study eligibility. A trained study staff member will obtain informed consent/assent and collect basic demographic, medical, psychiatric, and medication history. ASD diagnostic status will be established using either an administration of the Autism Diagnostic Observation Schedule (ADOS-2) [63] from within the last 2 years or the ADOS-2 newly administered by a research reliable study clinician. Similarly, IQ will be assessed using either an administration of a standardized cognitive assessment from within the last 2 years or the Wechsler Abbreviated Scale of Intelligence, 2nd Edition (WASI-II) [64] newly administered by a study clinician. A blinded evaluator will rate the Clinical Global Impressions Severity Scale (CGI-S). Caregivers will complete the Emotion Dysregulation Inventory, Revised (EDI-R) [65] to obtain ED study inclusion criteria. Caregivers also will complete the Vineland 3 [66], unless one was completed within the last 6 months. A full description of these and other measures is provided in Measures and Method of Data Collection.

Outcome visits In addition to their screening visits (T1), participants will complete assessments at four other time points: Week 0: Baseline (T2); Week 7: Post Active Treatment (T3); Week 16: Post Generalization (T4); and Week 29: Final Outcome Visit (T5). The list of assessments administered at each timepoint are described in **Measures and Method of Data Collection** and Table 2.

Upon program completion (T3), families will complete semi-structured interviews to elucidate barriers and facilitators, especially those related to disparities in access (i.e. due to socioeconomic status, rurality, racial and ethnic discrimination). Themes will be identified through future qualitative analyses and will be utilized to inform future dissemination and implementation trials.

Sampling

Participants will be 144 autistic youth enrolled and randomized to either RT ($N=72$) or AIMS ($N=72$). Given a 15% attrition rate observed in our initial pilot, we will enroll 144 participants in order to have 60 children complete each arm of the study.

Eligibility criteria Inclusion criteria include:

1. Confirmed DSM-5 diagnosis of ASD via the ADOS-2, completing either within the last 2 years or at Screening (T1) by a research reliable clinician.
2. 8–12 years of age, of any biological sex or gender identity.
3. Full-Scale IQ (FSIQ) ≥ 65 or other Wechsler IQ test completed within the last 2 years.
4. Clinically elevated ED as measured by a score ≥ 6 on the EDI-R.
5. Child and caregivers are fluent in spoken English. This criterion was implemented due to the group format (i.e., all participants needed to speak the same language) and insufficient availability of all assessment materials in languages other than English.
6. Child has fluent, functional, complex communication, defined as appropriateness of Module 3 of the ADOS-2.
7. Family is willing to keep prescribed medications and outside interventions stable. However, participants are *not required* to discontinue outside interventions.
8. Family willingness to participate in twice weekly, 90-minute sessions of either treatment condition.
9. The child's legal guardian must provide written informed consent and the child (for youth ages 11–12 years old) must provide written informed assent.

Exclusionary criteria include:

1. Initiation of new psychosocial/behavioral intervention within 30 days prior to randomization/first day of treatment.
2. To ensure group participants' safety, children will be excluded if they have exhibited any physical

Table 2 Regulating together (RT) curriculum

Session	RT Child Topics	RT Caregiver Topics
1	Group Rules, Introductions, and Emotion Identification	Introductions and Crisis Management
2	Relaxation Skills	Relaxation Skills and Functions of Behavior
3	Triggers and Body Signs	Triggers, Body Signs, and Prevention Strategies
4	Rating Emotions	Rating Emotions and Problem Sizes
5	Problem Sizes	Reinforcement Systems
6	Problem Solving	Problem Solving
7	Positive and Negative Thoughts	Positive and Negative Thoughts
8	Cognitive Flexibility	Cognitive Flexibility
9	Review	Community/Personal Supports, Treatment Planning
10	Graduation	Review, Treatment Planning, and Graduation
	Individualized Consultation following group completion	

aggression toward other children outside in the home in the two weeks prior to T1 resulting in injury. Other significant disruptive, aggressive, self-injurious, or sexually inappropriate behavior felt to be dangerous or overly disruptive to the group sessions will be reviewed by the study team on an individual basis.

3. Co-occurring, major neuropsychiatric disorders including substance use disorders, bipolar disorder, and psychotic disorders/schizophrenia.
4. Presence of major sensory impairment limiting unmodified participation in the material including blindness and uncorrected hearing loss.

Recruitment The first study participant was enrolled on September 8th, 2022. Recruitment of participants will be primarily conducted by notifying treating clinicians and agencies throughout Ohio, Kentucky, and Indiana, our hospital's neurodevelopmental outpatient and inpatient clinical services, and local schools who serve autistic youth of the availability of this program of research. This includes sharing the study opportunity with the 180 + person waitlist at our hospital who are waiting for autism related outpatient treatment. We also will work closely with personnel from our hospital's Department of Marketing and Communications and Community Engagement Core (CEC), whose resources will be enlisted to facilitate communication to the local and regional community (e.g., physician liaisons to area pediatrician offices, direct engagement with the neighborhood surrounding CCHMC).

The available historical and clinical data will be reviewed with the referring clinician, and if it appears that the participant would satisfy entry criteria for the study, the participant's legal guardian will be contacted to be provided information about the study. All potential participants' caregivers expressing interest will be screened via telephone by the primary study coordinator for diagnostic status, other co-occurring diagnoses, age and language criteria, and other presenting concerns (i.e., safety) before being scheduled for their initial in-person Screening visit (T1).

We plan to include females and members of minority groups consistent with nationwide and community rates and randomization procedures described below will ensure equal numbers are represented in both treatment conditions. To minimize barriers to participation, participants are compensated for transportation mileage. Additionally, childcare (e.g., for siblings), snacks, and drinks are provided during all treatment sessions.

Intervention

Study setting All intervention sessions and outcome assessments will take place in-person at Cincinnati Children's Hospital Medical Center (CCHMC), a pediatric academic medical center, except for the individualized consultation visit and the final outcome visit which both take place virtually via a secure telehealth platform. Treatment takes place in two group rooms, one for caregivers (Fig. 2A) and one for youth (Fig. 2B). Each group room has chairs, tables, and a whiteboard. The caregiver room is set up with tables in the middle for families to sit around while facing each other. Youth have two stations in their

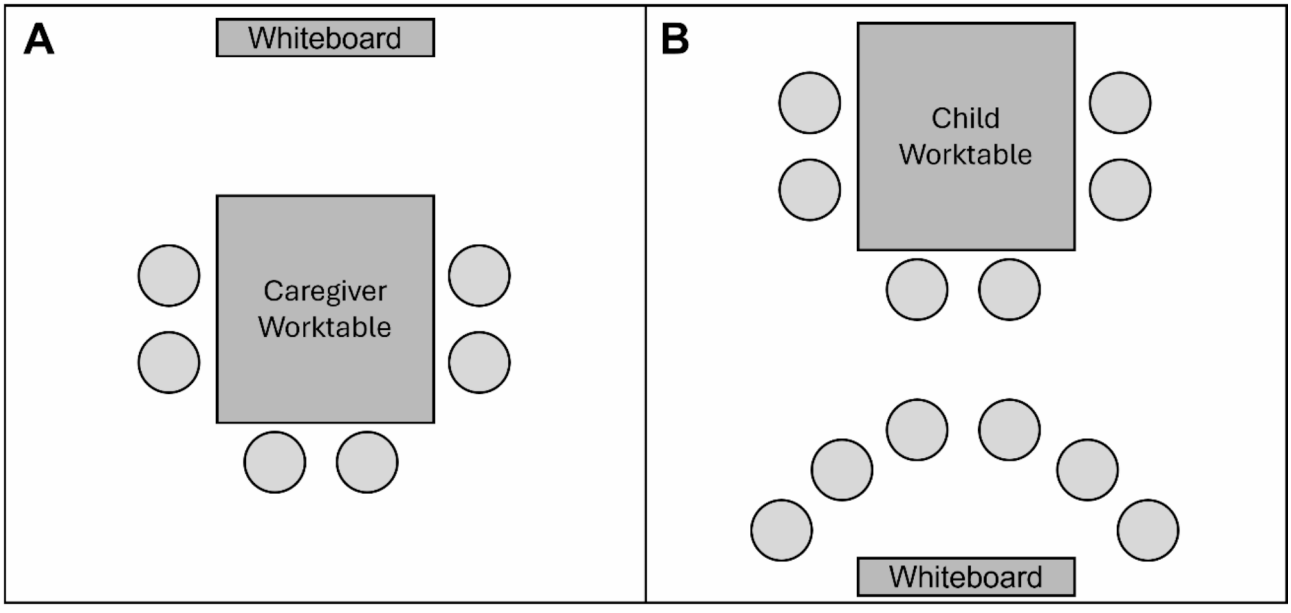

Fig. 2 Treatment room layout

Table 3 Assessment measures

Measure	Purpose	T1	T2	T3	T4	T5
Child Characterization						
ADOS-2	ASD symptoms	X				
WASI-II	Cognitive ability	X				
CGI Severity	Global severity	X				
Vineland 3	Adaptive behavior	X				
Dunn-Rankin Reward Preference Inventory	Reward preference		X			
Primary Outcome Measures						
Emotion Dysregulation Inventory– Reactivity	ED	X	X	X	X	X
Daily Phone Diary– Frequency and Intensity	Functional outcomes		X	X	X	X
Inpatient Hospitalization Rates	Functional outcomes		X			X
Secondary Outcome Measures						
Children's Organizational Skills Scale	AIMS outcome		X	X	X	X
Mindfulness Attention and Awareness Scale– Child and Caregiver forms	Mindfulness		X	X	X	X
Emotion Regulation Skills Test	Emotional regulation knowledge		X	X	X	X
BRIEF-2	ED		X	X	X	X
ABC-2	Irritability		X	X	X	X
PROMIS Anxiety	Anxiety		X	X	X	X
PROMIS Depression	Depression		X	X	X	X
Flexibility Scale	Cognitive flexibility		X	X	X	X
Probabilistic Reversal Learning	Cognitive flexibility		X	X	X	
CGI Improvement	Global change			X	X	X
Treatment Moderators						
Caregiver Readiness and Satisfaction	Readiness/satisfaction		X	X	X	X
Autism Specific Parenting Self-Efficacy Scale	Caregiver self-efficacy		X	X	X	X
Parenting Stress Index, 4th Edition, Short Form	Caregiver stress		X	X	X	X
Therapy Process Observation Coding System	Therapeutic processes/mechanisms			X		
Faros Cardiovascular Biosensor	HRV		X	X	X	
Qualitative interviews	Barriers to participation			X		

room. One has tables and chairs to complete worksheets, intervention activities, and snack. The second station has chairs arranged in a half circle in front of a white board, where the leader presents new information to the group. There are also clinical rooms for youth to separate and calm if needed.

Regulating together (RT) intervention The RT program meets twice weekly for 1-and-a-half hours over 5 weeks (10 sessions; 15 h of content) with concurrent child and caregiver groups. Each manualized RT child session focuses on teaching participants CBT and mindfulness skills and strengthening them via repeated practice. Each session includes review, relaxation, new material didactic, activities to reinforce material, mindfulness, and homework. Session topics for youth and caregivers are provided in Table 3. The manualized RT caregiver curriculum is structured similarly to the child group and is supplemented by well-established direct instruction rooted in parent management strategies. The individualized consultation at the end of treatment will focus on treatment planning and individualized plans to continue skill use at home during the Generalization Phase. During the individualized consultation, which both the child and caregiver attend virtually, the clinician will help the family identify the skills the child has made progress in and what they want to continue to work on from the group material.

AIMS (active control condition) intervention The ACC, Achieving Independence and Mastery in School (AIMS) was initially designed for middle schoolers, but was adapted for the 8–12-year-old age range of this study. AIMS emphasizes academic executive functioning and organizational skills. It is a group based manualized intervention targeting executive functions related to academic performance. AIMS is well-established and has been used with autistic youth in schools and in outpatient settings. It was chosen to replicate the time, duration, and structure of RT. AIMS is the ideal comparator as an ACC because it is equivalent to RT on primary non-specific factors including attention, dosage, and format. The AIMS treatment program will be 10 sessions focused on academic executive functioning/organizational skills. AIMS will *not* include a caregiver group as the caregiver group is viewed as an *active component* of the RT treatment. However, caregivers will receive handouts providing the material from the youth group. AIMS has face validity as an active control for RT for several reasons, includ-

ing structural equivalence and the addressing of potential executive functioning difficulties, an underlying cognitive process hypothesized to relate to ED. To parallel the RT program, group sessions will be conducted in a bi-weekly format (i.e., 2x/week, 5 weeks, 10 sessions), which has been approved of by the creators, Drs. Amie Duncan and Leanne Tamm. AIMS has been conducted multiple times a week in school settings. Additional adaptations were made to the curriculum make it more appropriate for the younger age group of this study including more visuals, more activities, an individualized reward plan, and simplified language. An individualized consultation appointment will be added following the completion of AIMS to mirror RT. During the individualized consultation visit for the AIMS condition, clinicians will focus on academic executive functioning/organizational skills.

Therapist training and fidelity Therapists for the interventions will be clinical psychologists, supervised post-doctoral fellows and doctoral students in clinical psychology, or clinical social workers. Two therapists will be needed for RT (youth group and caregiver group) along with a research coordinator who will serve as the behavioral assistant. The behavioral assistant will be a bachelor's or master's level trained individual who will assist with the group material or behavior management after completing training in RT and behavior management strategies. AIMS will require one therapist and one behavior assistant. RT and AIMS use the same pool of therapists and behavior assistants to help control for individual provider differences in implementation. Before beginning the trial, each therapist and behavior assistant will complete a 2-day training (1 for RT, 1 for AIMS) that will cover both RT and AIMS. Both RT and AIMS have explicit directions and scripts for the therapists to follow as well as general directions for behavior and environmental management. All group sessions will be video recorded and one entire round of 10 sessions for both RT and AIMS will be reviewed for newly trained therapists with feedback provided by the PI (RS) on fidelity and behavior management. Once the initial training period is complete, 20% of videos will be reviewed for fidelity to the treatment manual. Fidelity coding will also ensure that no element unique to RT were covered in the AIMS groups. Fidelity tracking has been created for both RT and AIMS and will be utilized for this trial. Ongoing group supervision will occur weekly.

Group assignment and randomization Following the screening visit, potential participants who meet study criteria will be randomized into the RT program or the active control AIMS program. A total of twelve blocks of twelve participants will be used. Within each block participants will be randomized to either RT (6 participants) or AIMS (6 participants). The order of our heart rate variability tasks (Rest/Baseline, Breathing, Relaxation; see below for task description) also will be randomized among the twelve participants in each block.

Randomization will be accomplished using SAS ® version 9.4 (SAS Institute Inc., Cary, NC). Specifically, the uniform random number generator will be used with a seed input from the study biostatistician (PH). The randomization sequence will be concealed from all study personnel except for our biostatistician (PH) and PI (RS). We will attempt to stratify by sex and minority status to ensure that an equal number are in both RT and AIMS. For the randomization procedures, it is assumed that 50% of participants are females and that 15% of participants are racially/ethnically minoritized.

Blinding All outcome assessors and data analysts will be blinded to participant treatment assignment until analyses are finalized and ready for dissemination. Due to the nature of the interventions (behavioral therapies with delivered content that openly communicates treatment condition assignment), blinding is not possible for study interventionists, fidelity raters, therapeutic relational raters (see Therapy Process Observation Coding System described below), participants, and caregivers.

Voluntary withdrawal of participants A participant may voluntarily withdraw at any time and for any reason. If a participant withdraws, at his or her request or at the request of his or her caregiver, the reason(s) will be recorded in the participant's source documentation. Participants who withdraw from the study prematurely will undergo all end-of-study assessments (T4) where possible. If a participant refuses to continue with study procedures, the reason for refusal will be fully documented in the participant's source document. Participants who withdraw from the study prior to completing the final follow-up visit may be replaced at the discretion of investigator.

Data collection, management, and analysis

A multi-method, multi-informant assessment battery (Table 2) will be used to provide accurate sample characterization, examine efficacy of RT (Aim 1 and 2) and identify potential facilitators of treatment response (Aim 3). All measures are appropriate for use with participants from racially/ethnically diverse backgrounds. In addition to these standardized characterization measures, adverse event data is collected following each therapy session and at each outcome visit (i.e., caregivers report any youth hospitalizations).

Characterization measures

The **Autism Diagnostic Observation Schedule, 2nd Edition (ADOS-2)** [63] is a well-established autism

diagnostic assessment. Module 3 of the ADOS-2 will be administered to all participants at the screening assessment to confirm ASD diagnosis, or a previous ADOS-2 will be used (as stated above).

The **Weschler Abbreviated Scale of Intelligence Second Edition (WASI-II)** [64] provides a brief and reliable measure of cognitive ability for individuals ages 6–90 years. The four-subtest full-scale IQ (FSIQ) will be used to assess global intellectual functioning. A FSIQ ≥ 65 is required to participate due to the cognitive requirements of both treatment conditions.

The **Clinician Global Impressions- Severity(CGI-S)** [67] provides a qualitative measure of global severity through a rating from 1 to 7 (1 = normal, not at all ill; 2 = borderline ill; 3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill; 7 = among the most extremely ill patients). The CGI-S will be utilized as a clinician-rated measure to assess severity of impairment in relation to ASD. A trained, independent clinician will rate the CGI-S at the Screening visit. The CGI-Improvement (CGI-I) also will be rated at follow-up visits and is described below; the same rater completes the CGI-S and CGI-I whenever possible. Rater training will be conducted with gold standard vignettes and inter-rater reliability of 80% will be required for all raters on our team.

The **Vineland Adaptive Behavior Scales, 3rd Edition (Vineland 3)** [66] is a well-established standardized measure of adaptive behavior that assesses skills in the Communication, Daily Living Skills, and Socialization domains. Caregivers will complete the Parent form. Standard scores from the Adaptive Behavior Composite and all three domains will characterize baseline adaptive behavior functioning.

The **Dunn-Rankin Reward Preferences Inventory** [68] is a 40-item child self-report that shows the type of rewards that a child prefers based on their choice between 2 types of rewards. Children in both conditions will complete the inventory. Caregivers in the RT condition will use the inventory during Session 5 (Reinforcement Systems) to help design a reward plan. Caregivers in the AIMS condition will use the inventory to help identify rewards for use during the program. Results from the Dunn-Rankin Reward Preferences Inventory will be shared with clinicians in both conditions to help them promote compliance during sessions.

Outcome measures

The **Emotion Dysregulation Inventory** [65] is the primary outcome measure for Aim 1. The EDI Reactivity Subscale (EDI-R) was chosen based on its close association with ED and evidence of treatment sensitivity (based on derived effect sizes from preliminary studies). The EDI consists of two scales: the EDI Reactivity scale (EDI-R), which captures poorly regulated negative emotional responses, and EDI Dysphoria scale (EDI-D), which captures negative affect and lack of motivation. The EDI-R is a primary outcome measure and EDI-D is a secondary outcome measure. Theta scores will be analyzed. The EDI has shown good internal consistency (α ranging from 0.90 to 0.97) and test-retest reliability [69, 70].

The **Daily Phone Diary (DPD)** was adapted using processes taken from studies of medical adherence [71, 72], with the content (i.e., questions, variables of interest) modified to probe for ED-associated behaviors. The DPD will review a 24-hour period on both a weekday and a weekend day through a cued recall interview conducted by an interviewer (trained research coordinator, not involved in treatment) to track the experiences and behaviors of youth and families. Families will be provided with an explanation of what an ED-related outburst is and what behaviors or emotions are of interest. Specifically, they will report on any of the following: aggression, self-injury, mood swings, intense reactions, tantrums, "0 to 60" emotional episodes, crying or being angry for more than 5 min, inability to calm down, being irritable or on edge, or damaging or destroying property. They will be asked for the approximate length in minutes of the episode, rate its intensity on a 5-point scale for each episode, and share how the child eventually calmed down, including whether assistance was needed. The frequency (total number of the above behaviors, summed across weekend and weekdays) and average intensity of reported behaviors will be analyzed.

Inpatient hospitalization rates will be examined through chart review and caregiver report for the number of psychiatric hospitalizations. Frequency of inpatient hospitalization will be assessed at two timepoints: at Baseline (T2; characterizing frequency of hospitalizations in the 6 months prior to enrollment in the study) and at the long-term follow-up assessment (T5; characterizing frequency of hospitalizations in the 6 months after completion of the individualized consultation).

Secondary outcome measures

Secondary outcomes measures were chosen to capture constructs closely related to, but not direct measures of, ED and/or those which found small to medium effects in our previous studies [58, 59, 73, 74].

The **Children's Organizational Skills Scale (COSS)** [75] is a rating scale completed by caregivers which yields three factors measuring Organized Actions, Task Planning, and Memory and Materials Management. The COSS will be used to assess treatment response to the AIMS intervention. The COSS has demonstrated good internal consistency (α ranging from 0.89 to 0.91) and test-retest reliability (α ranging from 0.94 to 0.99) [75]. T-Scores will be used in analyses.

The **Mindfulness Attention and Awareness Scale (MAAS)** [76] is a 15-item questionnaire that measures key aspects of mindfulness, including receptive awareness and attention to the present moment. This measure will be completed by self-report. The child version will be completed to assess child mindfulness, and the adult version will be completed by caregivers to assess caregiver mindfulness. The total scores will be used in analyses. The MAAS has shown good internal consistency in children ($\alpha = 0.84$) [77] and adults ($\alpha = 0.87$) [76].

The **Emotion Regulation Skills Test (ERST)** was created for RT to measure knowledge of skills taught in RT to manage ED and is available upon request to any qualified professional. It is composed of 14 multiple choice questions reflecting key ideas or skills presented in each session. Each item is scored as correct or incorrect. The total percent correct items will be analyzed. ERST was sensitive to change with intervention in our previous trial ($p < 0.0001$, $d = 0.92$).

The **Behavioral Rating Inventory of Executive Functioning, 2nd Edition (BRIEF-2)** [78] is an 86-item, caregiver-report inventory that measures EF skills in children ages 5–18 years. It is scored on a Likert scale from 1 (Never) to 3 (Often) and it contains eight subscales. The T-score from the Emotional Regulation Index will be analyzed. The BRIEF-2 has shown good internal consistency (α ranging from 0.76 to 0.96) [78].

The **Aberrant Behavior Checklist, 2nd Edition, (ABC-2)** [79] is a 58-item caregiver-report questionnaire on behavior difficulties commonly seen in individuals with neurodevelopmental disabilities like ASD. It is comprised of five subscales derived by factor analysis; the total raw score of the Irritability subscale will be analyzed given it is a construct closely related to ED and has been used in previous RT trials. 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-2 has shown good internal consistency (α ranging from 0.77 to 0.94) in ASD [80].

The **Pediatric PROMIS Anxiety (13 items) and Depression (13 items) Scales** [81, 82] are self-report measures developed as part of the National Institute of Health Patient-Reported Outcomes Measurement Information System (PROMIS®) program to assess symptoms of anxiety and depression in youth 8 to 17 years of age. T-scores from both scales will be analyzed. Both versions of the Anxiety scale (parent $\alpha = 0.91$; child $\alpha = 0.96$) and Depression scale (parent $\alpha = 0.85$; child $\alpha = 0.93$) have shown good internal consistency.

The **Flexibility Scale** [83] is a caregiver report measure developed to assess the multidimensionality of flexibility in youth with ASD, including cognitive aspects of flexibility in daily life, routines/rituals, transitions/changes, special interests, social flexibility, and generativity. The Flexibility Scale has demonstrated good internal consistency (α ranging from 0.750 to 0.906) and construct validity [83]. The total raw score of the Flexibility Scale will be analyzed.

The **Probabilistic Reversal Learning Task (PRL)** is a measure of cognitive flexibility which has previously been validated for use in children with ASD, including as a treatment outcome measure previously detailed [74, 84, 85]. Full technical specifications are provided in our previous reports [74, 84, 85]. Briefly, participants complete two practice tests to establish test comprehension and are then instructed to choose one of two identical stimuli (i.e., animals) positioned in different locations on the screen. They are rewarded (i.e., computerized coin) on 80% of correct responses and on 20% of incorrect responses. During the "acquisition phase", participants choose one of two stimulus locations until they have identified the correct location on 8 of 10 consecutive trials. They then proceed to the "reversal phase" in which the correct location is switched without warning, and they must identify the new correct location on 8 of 10 consecutive trials. Testing is discontinued if they do not reach criterion within 50 trials of either phase. Error-related outcomes from the PRL task have previously demonstrated moderate test–retest reliability (ICC = 0.66–0.70) [74]. We will analyze the number of errors separately for acquisition and reversal phases. Research staff administering the PRL task undergo initial training and regular reviews for administration fidelity.

The **Clinician Global Impressions- Improvement (CGI-I)** [67] will assess response to treatment. A trained, independent clinician masked to group assignment will rate the CGI. The CGI and the reliability process are described above. The CGI-I provides an aggregate measure of treatment response through a rating from 1 = "very much improved" to 7 = "very much worse" that will be analyzed.

Treatment moderator measures

The **Caregiver Readiness and Satisfaction Survey (CRS)** was created by our team to measure caregiver readiness for treatment, confidence in managing their child before treatment, and confidence and satisfaction following treatment. It is available upon request to any qualified professional. Answers are rated on a 6-point Likert scale ranging from 0 ("not at all") to 5 ("a great deal"). This survey was created specifically for RT and has been utilized throughout pilot testing. The total score will be analyzed.

The **Autism-Specific Parenting Self-Efficacy Scale (PSEaS)** [86] is a 17-item measure of caregivers' confidence in managing parenting challenges related to ASD. This measure specifically evaluates confidence related to interventions and advocacy challenges. The PSEaS has

shown strong internal consistency (α = 0.91) [86]. The total score of the PSEaS will be analyzed.

The **Parenting Stress Index, 4th Edition, Short Form** (PSI-SF) [87] measures the magnitude of stress in the parent-child system. It includes three domains of stress including child characteristics, parental characteristics, and life stress. Internal consistency is high and test-retest reliability is satisfactory [87]. The PSI-SF has been utilized in ASD to measure caregiver stress with the Parent Distress Scale demonstrating the strongest sensitivity to change and ability to measure distress in caregivers of children with ASD. T-scores from the Parent Distress Scale will be analyzed.

The **Therapy Process Observation Coding System (TPOCS)** has been widely used to measure relational processes found to be associated with treatment outcome: therapeutic alliance (TPOCS-A) [88] and group cohesion (TPOCS-GC) [89]. In-session participation (engagement) assesses cohesion among group members, energy, and positive affect. For this study, external raters from the team of our collaborator, Dr. Susan White, will be unaware of study hypotheses while rating securely transmitted video recordings of select sessions. The TPOCS-A has shown good internal consistency in children (α = 0.95) and caregivers (α = 0.89) as well as high stability over time, convergent validity, and predictive validity [88]. The TPCOS-GC has shown acceptable internal consistency (α = 0.77), as well as moderate stability over time, good discriminant validity, and fair predictive validity [89]. For each treatment block, one session's video will be randomly selected (PH, our biostatistician, maintains the randomization sequence for video selection) for coding from early in the intervention (Sessions 1–3), the middle of the intervention (Sessions 4–7), and the end of the intervention (Sessions 8–10) for a total of three videos/sessions for each block. Sessions are selected in this manner to capture changes in therapeutic alliance and group cohesion that occur across the group therapy sessions. All children and caregivers from each video will be rated using the TPOCS. Children in the AIMS ACC also will be rated using the TPOCS.

Participant **heart rate variability (HRV)** [73] will be measured using the ambulatory and waterproof Biomation 180° eMotion Faros™ Cardiac Monitor across three tasks (Baseline/Rest, Relaxation, Breathing). Data collection methods are identical to those that we have previously detailed in our pilot trial of RT which found that HRV predicted treatment response [73], except for the length of each condition; for this study, HRV will be collected at rest (3 min of passive video viewing), during unstructured relaxation (3 min), and during guided deep breathing (3 min). The Farros cardiovascular monitor is specifically developed to record high quality electrocardiographic signals while participants are active or in motion. The form factor is compact, lightweight, and designed to wear continuously and unobtrusively. It samples ECG up to 250 Hz, and HRV to 1000 Hz, which is sufficient for research. During T2, T3, and T4, study personnel will record the start and end times using a stopwatch synchronized to the system clock in the Faros. These records will enable precise segmentation of cardiovascular data, enabling cross-condition analyses within-session and across-session change over time. Caregivers will also complete a log to report information that may affect physiological measurements, including participant's sleep the night prior, stressors that may have occurred that day, and changes to medications or physical health status. Test-retest reliability for HRV outcomes from our past pilot of RT ranged from good to fair (Rest/Baseline ICC = 0.72; Relaxation ICC = 0.62; Breathing ICC = 0.55) [73]. The order of HRV tasks (Rest/Baseline, Breathing, Relaxation) will be randomized and counterbalanced across all participants. Research staff administering the HRV task undergo initial training and regular reviews for administration fidelity.

Data management A rigorous and systematic approach to data management is critical for the quality of this study. We will devote substantial effort and commitment to data collection and to edit, verify, correct, update, and assemble the resulting data files. Our data management system incorporates quality control at every possible step from data collection to data analysis. The PI and primary research coordinator will be responsible for data collection and accuracy of record keeping. The PI also will be responsible for establishing and maintaining ethos that data management procedures are of the utmost importance.

REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources. REDCap is a PHP web application served by Apache Tomcat over a 128 bit SSL connection using a signed certificate. Data primarily will be collected via REDCap on tablets when possible, but will be collected on hard copy when not possible. When data is entered directly onto the tablet via REDCap, there are less opportunities for scoring, storage, or entry errors. When a hard copy must be used, data entry will be verified by data entry personnel. Data personnel will be trained to search for potential errors and any questionable or illegible entries will be brought to the attention of the study team member responsible for completion of the form. All questionable or illegible entries

will be addressed promptly. Corrections to paper records will be made in a way that allows the original entry to be understood. Corrections to electronic records will be recorded with an audit trail that allows the original entry to be retrieved.

Original research records and source documents will be maintained in a research chart and stored in a locked file cabinet, in a locked room, on a secure floor with staff only access. Records will be kept secure, and individually identifiable information will not be included in any reports or data sets. Only the PI and members of the research team will have access to these files, ensuring the security of the records. All procedures to ensure confidentiality will follow institutional regulations and policies. Data from hard copy or electronic forms or from computerized cognitive tasks and cardiovascular data will be entered from the respective source into our secure electronic database by the study coordinator or delegated study team member. The PI and/or other members of the study team will review case report forms and database entries for accuracy by comparison with the source documents. Of note, computerized cognitive tasks and Faros cardiovascular data will be collected electronically, will undergo necessary pre-processing steps by the CCHMC research coordinator or other qualified research personnel, then will be verified by the respective research scientists. CCHMC uses a central database housed through the institution. The CCHMC Central REDCap database will be built upon a developmental disability-focus clinical trial REDCap database. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by the research team.

Data will be entered then checked and verified against the Case Report Forms (CRFs) by a different Good Clinical Practice (GCP) trained research coordinator. All data will be double-entered and verified by trained personnel. In addition, a postdoctoral fellow or trained study coordinator will review all computer based cognitive assessments on a monthly basis to ensure fidelity of data collection and all heart rate data will be sent to external collaborators on a monthly basis. All group videos will be securely sent to external raters for therapeutic process coding (TPOCS) at the end of each group round.

All data for each participant will be labeled with a unique ID number. These data from the protocols will be entered into a secure database on the hospital's server. An electronic key that links the participant ID numbers to identifiable information in the physical files will be stored in the PI's private lab folder on the hospital's server. This electronic key will ensure that a participant's electronic data can be quickly located and deleted in the event that the participant requests the destruction of their data upon withdrawal from study. Study investigators may utilize all previously collected data from time of consent up to the subject withdraw, unless otherwise and specifically requested, verbally or in writing, by the subject, and communicated, in writing, to the sponsor and central readers. All principal investigators and co-investigators, the central readers, and employees of the sponsor will have access to the coded data and study results. All investigators and the sponsor will have access to the database with coded scores. Physical data obtained from participants will also be housed by the PI at the institution for three years after the IRB is closed. If at any time, during or after the conclusion of the study, a participant requests that their data not be used, the PI will immediately destroy all physical data housed at the institution. The PI will only destroy data if a participant or their legal representative asks for them to do so.

Statistical methods and data analysis

Aim 1: Evaluate the effectiveness of RT To test short-term efficacy, a series of repeated measures ANOVAs will be conducted by testing the within-subjects factors of time (i.e., T2/Baseline vs. T3/Post-Active Treatment) on each of the outcome measures (Table 2). A series of repeated measures ANCOVAs also will be conducted to test the same effects while co-varying for sex. We hypothesize that, relative to the ACC, the RT group will demonstrate significant improvement in ED (reduced scores on the EDI-R; reduced frequency and intensity of outbursts reported on the Daily Phone Diary) when comparing Baseline (T2/Week 0) to the Post Generalization Phase (T4/Week 16).

Aim 2: Assess the maintenance of treatment gains To test the long-term efficacy of RT, a series of repeated measures ANOVAs will be conducted by testing the within-subjects factors of time (i.e., T2/Baseline vs. T4/Post Generalization Assessment vs. T5/Final Outcome Visit) on each outcome measure. We will conduct the same tests while co-varying for sex. We hypothesize that, relative to ACC, the RT group will demonstrate maintenance of gains in ED (EDI-R; Daily Phone Diary) from Baseline (T2/Week 0) to the Post Generalization Assessment (T4/Week 16) and the long-term Final Outcome Visit (T5/Week 29). We also hypothesize that, relative to ACC, the RT group will have fewer psychiatric hospitalizations 6 months after completion of the individualized consultation compared to the 6 months prior to study enrollment.

Aim 3: Determine the moderating factors that enhance or diminish treatment success We will use mixed effects models to determine if participant factors moderate the effects of the RT intervention. For each outcome measure, a variable accounting for assessment points (i.e., one of the combinations of assessment points described

for Aims 1 and 2) will be entered at level-1 of the model, and one of the possible moderators (i.e., IQ, treatment factors, child factors, or parenting factors) will be entered at level-2. The cross-level interaction between assessment points and the moderator will be the direct test of Aim 3 for moderation. We hypothesize that greater child (e.g., greater heart rate variability, ED severity as measured by the EDI-R) and caregiver (e.g., greater self-efficacy, lower stress) factors will predict greater treatment efficacy. Qualitative data from semi-structured interviews with caregivers at the end of active treatment will identify barriers and/or facilitators (e.g., socioeconomic status, family dynamic, time, rurality, race) to treatment access, impact, and sustainability (see Discussion for barriers and solutions identified thus far).

Power analysis Power analyses found that the models described for Aims 1 and 2 (alpha = 0.05, power = 0.80, $N = 60$ participants) would be powered to detect an effect of Cohen's d = 0.36, a smaller effect than was found in the preliminary treatment study (d = 0.50). A power analysis of the models described for testing Aim 3 using these same parameters found that the models would be powered to detect a cross-level interaction effect of d = 0.30 or larger (i.e. between a small and medium effect size), indicating that a clinically meaningful effect would be detectable.

Monitoring, risks, and protections

Data monitoring and auditing We will have a Data and Safety Monitoring Board (DSMB) to ensure the study is conducted in a manner minimizing all risks to participants and data integrity. It will include three experts including an autism expert (Ryan Adams, PhD), a clinical trials expert (Leanne Tamm, PhD), and a statistician (Bin Zhang, PhD). The board will be chaired by Ryan Adams and will meet every 6 months during the project to review outcome data collection. If concerns arise related to participant safety or data integrity, the DSMB can meet more frequently. The tasks of the DSMB are to review and report any adverse events, devise and adapt risk management protocols, and discuss any concerns that may arise regarding data integrity or participant confidentiality.

Harms Minor risks are those associated with the potential for loss of confidentiality. There are minor risks associated with discomfort in discussing personal matters during assessment and intervention periods. During the conduct of clinical research, personal information about the participant or family could become known to others against the participant's wishes. These episodes are not common, but occasionally occur due to the large number of different people that may interact with the participants or family members during a course of a clinical trial with frequent visits at a large hospital. Acquiring the behavioral and treatment records and video of the participants creates the potential risk of breach of confidentiality. In unusual cases, the mandatory reporting of certain events (e.g., child abuse or neglect, see below) would be required by law. Group-based intervention provides additional risk of breach of confidentiality by other group members. All participants will be notified of this risk during consent and group members will be encouraged to keep all information from other group members confidential.

Beyond those risks noted above, there are minimal risks associated with office visits and the collection of behavioral data. This would include the inconvenience of the frequency of study visits and potential embarrassment over discussing psychiatric symptoms or emotional experiences. In addition, autistic youth and caregivers may feel embarrassed or uncomfortable sharing their ED difficulties in the group therapy session. This is explained in the consent as a possibility. However, there are no substantial risks involved with participating in either RT or AIMS.

Since almost everyone has difficulty with some of the neuropsychological testing, participants may be concerned if they are unable to perform well on all the tests or may feel frustrated or anxious while completing the tests. Trained staff will help validate feelings and provide breaks if needed.

Children and their parents/guardians who participate may be asked questions that make them uncomfortable or cause embarrassment. They will be told at the beginning of the study visit and reminded during the study visits that they do not need to answer any questions that they do not wish to answer and that they can stop the research at any time. Most questions and measures used in the study are standard for medical or psychological evaluations and therefore have minimal risks associated with them. Parents/guardians are free not to answer any questions to which they object.

Should a child become a danger to themself, others, or objects, physical intervention may be deemed necessary. Physical intervention is only used in the event that all other de-escalation techniques have failed. Though we believe the risk of this occurring will be minimal since participants who have engaged in physical aggression towards children resulting in serious injury within the past two weeks will not be eligible for enrollment, given the nature of the program and social environment, it is possible.

Protection against risks Effective screening (using medical history and interview) will be used to exclude participants who are at greatest risk. Participants will only be accepted into the study if they are free of any significant medical illness as determined by a comprehensive history taking, medical review of systems.

We have several mechanisms to reduce the risk of loss of confidentiality described above in Data Management. Additionally, all written information will be kept confidential and separate from their medical chart. All data and information accumulated in person, through observation, video, photograph, survey, or via checklist, pertaining to the participant will only be discussed and shared with the participant and necessary personnel and agencies. Participant information will not be individually identifiable in published manuscripts.

Finally, the minimal risks associated with office visits will be reduced even further. The guiding principle in all interactions is respect for the dignity of each participant and their family. The scheduling of study visits takes into account school and work schedules to minimize the disruption for the participant and family. All procedures will be explained verbally or by demonstration prior to their completion. Whenever possible, the least restrictive intervention will be utilized to manage disruptive behaviors that occur during *Regulating Together* or academic executive functioning skills training. Due to the emphasis the *Regulating Together* curriculum places on independent self-regulation, behavior management strategies naturally differ between the RT condition and ACC (i.e., youth demonstrating dysregulated behaviors in the RT condition may be prompted to use strategies they learned in the group). Since children with significant disruptive behavior that has caused injury to another child in the past two weeks will be excluded from participation, we do not expect participants to exhibit any severe maladaptive behaviors. Disruptive behavior will initially be handled by redirection. Should behaviors occur that threaten to jeopardize the safety of participants or staff, crisis intervention-trained staff may utilize de-escalation and self-protection as prescribed by the TCI model.

Response procedures for serious events One serious adverse event a participant may encounter is the requirement by health professionals to report to authorities any instances of suspected physical abuse, neglect or threat of physical harm among participants to themselves or others. In addition, aggressive behavior may occur, although is not anticipated, during the group treatment. To anticipate these concerns, the project has established procedures and guidelines to respond to risk disclosures and crisis situations among participant families. Assessment staff will be trained to recognize risks or crises that require immediate reporting response. Each of the possible adverse events is described in detail, including background, criteria for emergency action, and non-emergency action. Please note, in each case, the project's PI will be notified first, so that they are fully informed of the situation.

Suicidal ideation or intention to harm self In the unlikely event that the content of the interviews, questionnaires, or group treatment causes emotional or psychological distress the PI, a licensed clinical psychologist, will be available at any time. However, if a respondent spontaneously reports immediate intent to commit suicide, researchers will follow the following procedures:

1. **Emergency**: in the rare instance that a child or parent is in imminent danger and needs emergency medical or mental health services, the researcher will request immediate assistance from the PI to determine if they need to call 911. Likewise, if a participant reports that he/she is thinking of dying by suicide and has a plan to do so, this will be considered an emergency and the interviewer will request immediate assistance from the PI and determine if they need to call 911. The researcher will immediately call the PI and write an incident report the same day. If the researcher is unable to contact the PI within 15 min, the researcher will call 911.
2. **Non-emergency**: If a parent spontaneously reports that he/she is suffering from depression, anxiety, or another mental illness and would like help, or indicates that they feel as though they "can't go on," the researcher will say, "You seem to be having a difficult time. If you think this is an emergency, you can call 911 or the CCHMC Psychiatric Intake Response (PIRC) Unit at 513-636-4124. If you think you need help with this problem, you can talk to your doctor." The researcher may also provide the participant with a written list of mental health referral numbers and suggest that they discuss feelings with their primary care physician or with a mental health specialist on the referral list. The researcher will call the PI within one hour of this incident. The PI will determine whether further action is needed in consultation with CCHMC legal counsel as necessary. An incident report will be written to the CCHMC IRB.

Intent to harm others. Researchers will not probe for this information during the session, but sometimes threats may be voiced spontaneously. If this is a vague statement about intent to harm others or retribution and it is not an identifiable person and/or the participant does not communicate clear intent, capable means, or immediate intent to do so, the researcher will redirect the participant. There is no need to file an incident report in these cases. However, if the participant makes a specific threat to a reasonably identifiable person, then the researcher will remind the participant about the limits of

confidentiality, avoid probing for specific intentions, and redirect the participant.

1. **Emergency**: In the rare instance that a person is in imminent danger and needs emergency medical or mental health services, the researcher will request immediate assistance from the PI on this study and determine if they need to call 911. An immediate report to the PI is required, followed by a written incident report the same day. If the researcher is unable to contact the PI within 15 min, the researcher will call 911.
2. **Non-emergency**: If a participant reports intent to harm others that is non-emergent in nature but that still communicates a reasonably identifiable person, clear intent, capable means or an immediate intent to do so, the researcher will contact the study PI within one hour and will complete an incident report the same day. In addition, the researcher will talk to the participant in private to express concern, encourage him/her to tell someone, and if he/she is a minor, inform him/her that we must report this to the study PI who may have to report it to a parent or guardian. The study PI will also consult with CCHMC legal counsel, as necessary, to determine what further action, if any, needs to be taken.

Intent to harm self or others in the group treatment The structure of the group setting is intended to prevent any intent to harm to self or others with emphasis on relaxation strategies, structure, and reinforcement of appropriate behavior. Researchers will not probe for information about intent to harm others during the session and it is not part of any of the research tasks. Sometimes threats may be voiced spontaneously. If a participant makes a vague statement about intent to harm others in the group, the researcher will redirect the participant. There is no need to file an incident report in these cases. However, if the participant makes an attempt to harm another group member, self, or property during treatment, the researcher will call an institutional "Code Violet" (the CCHMC public address system code requesting assistance for a patient or family member who presents a danger to themselves or others) and follow hospital procedures for a Code Violet. The safety of other group members will be the primary goal of any intervention. If a Code Violet is called, an immediate report to the PI is required, followed by a written incident report the same day. Typically, children calm quickly when given space, time, and quiet away from other group members. Caregivers are always asked to come into the room if a child escalates to assist with calming. This is a rare occurrence in RT, but has occurred. If needed, other children are moved to a separate room to continue learning and completing the session.

Child abuse/neglect Researchers will not probe for this information during the session and it is not part of any of the research tasks. All study staff are mandated reporters of suspected child abuse/neglect. However, if a participant discloses that either a child is being sexually, physically, or verbally abused or there is evidence of neglect (e.g., young child left alone for hours), the research coordinator will contact the PI who will address this with the following steps:

1. **Emergency**: In the rare instance that a child is in imminent danger, the researcher will request immediate assistance from the PI on this study and determine if they need to call 911. An immediate report to the PI is required followed by a written incident report the same day. We will also consult with CCHMC legal counsel to determine what further action needs to be taken.
2. **Non-emergency**: If there is a report or incident of child abuse that is non-emergent in nature, the researcher will consult with the study PI by phone within one hour of the incident and will complete a written incident report the same day. We will also consult with CCHMC legal counsel to determine what further action needs to be taken.

Ethics and dissemination

Ethical approval All study procedures have been approved by the Cincinnati Children's Hospital Medical Center (CCHMC) Institutional Review Board (IRB00000231).

Protocol amendments All protocol amendments will be reported to the funding agency (United States Department of Defense) and will require IRB approval. Any protocol amendments occurring after the publication of the present manuscript also will be described in detail in manuscripts reporting study findings. Substantial protocol amendments that require the reconsenting of participants (as deemed necessary by our IRB) will be described to participants during reconsenting procedures, although this has not yet occurred.

Consent and assent procedures Potential participants and their legal guardians will have a face-to-face interview study staff where the nature of the project, the risks, the benefits, and the alternatives to participation in the project are discussed with the participant (when possible) and the participant's family. If, following these discussions, the participant and family remain interested in the project, assent will be obtained from the participant (for youth

ages 11–12 years old) and formal written consent will be obtained from the parent(s)/legal guardian(s). All participants and their legal guardians will be provided with copies of the consent form for future reference. If consent or assent is withdrawn prior to completion of the study, the reason for withdrawal will be documented. This will not affect the participant's ability to receive clinical treatment for their condition either at our center or elsewhere.

Confidentiality Participant confidentiality is paramount to the research process and the PI and study team will make every effort to ensure confidentiality is maintained throughout the study. Loss of confidentiality is a potential risk in most clinical research. During the conduct of clinical research, personal information about the participant or family could become known to others against the participant's wishes due to the nature of the intervention (i.e., group therapy). Acquiring the behavioral and treatment records and video of the participants creates the potential risk of breech in confidentiality. In unusual cases, the mandatory reporting of certain events (e.g., child abuse or neglect) would be required by law. All visits are conducted in private offices, study rooms, and classrooms. Additionally, other procedures to ensure confidentiality (see Protection Against Risks) will follow the regulations and policies set by CCHMC, including those of the Health Insurance Portability and Accountability Act (HIPAA).

Ancillary and post-trial care Referrals for other behavioral health or medical services will be provided upon participant request at any point during or after their participation. This is commonly addressed during Session 9 of the caregiver curriculum (Community/Personal Supports and Treatment Planning) and during the individualized consultation.

Dissemination policy All data will be reported in the public domain as appropriate. It is essential that, following data collection, the data is analyzed quickly and efficiently, and that the data is presented in abstract/lecture format and presented in peer review journals. Additionally, the research team provides research-based testing results including IQ testing, autism testing, and adaptive behavior testing to participants. Over the course of this project, the primary methods for data sharing will be via scholarly publications, presentations at professional conferences, and, as findings permit, disclosure of nonspecific summary data to professionals and the general public. To the extent feasible and appropriate, we will share pre-publication findings with colleagues who have a demonstrable, legitimate scientific interest and/or clinical interest that may be addressed by research findings. Authorship eligibility will be determined based on individuals making a substantial scientific contribution to the reported study and results. We do not intend to use professional writing services when reporting results, outside of the use of in-house journal editors and typesetters.

Where raw and analyzed data may be useful to other researchers in understanding or reproducing work, we will make strong efforts to furnish those data within six months of the close of the study. To make data available, investigators will de-identify data and follow IRB-approved procedures. We have structured informed consents so that acquired data, once de-identified, can be shared. If situations arise wherein data cannot be de-identified, but may be of significant scientific value, researchers will be encouraged to set up procedures that allow qualified researchers who complete appropriate training procedures to request access to the data. We also will submit data collected over the course of the project to the National Institute of Mental Health Data Archive (NDA), a secure bioinformatics platform for data sharing of information, supported by the National Institutes of Health (NIH).

Discussion

The goal for this RCT is to meet the urgent need for interventions targeting ED in autistic youth. This study represents the first time that RT will be compared against another active treatment condition. Following the completion of this trial and pending positive results, we will pursue further implementation work and continue our dissemination efforts. Providers interested in RT training opportunities can contact our team at https://regulatingtogether.com/contact/.

Participant recruitment is ongoing, and several blocks of treatment have been conducted. As we have monitored study challenges, two changes to the original protocol have been made. First, the original ACC was the Testbusters program, a program that teaches study skills and test-taking strategies [90] and which has a narrower focus relative to the AIMS program that now serves as our ACC. The transition to AIMS as our ACC was made following recruitment for the first treatment block when multiple participants withdrew from the study upon treatment assignment, raising concerns for non-random attrition. Participants voiced their reluctance to participate in an ACC not specifically tailored to ASD and that exclusively focused on study skills. AIMS was selected as the new ACC because it was designed for autistic youth and addresses executive functions more broadly. There have not been challenges with attrition following this transition. Second, participants were originally given the choice of completing the individualized consultation visit either in-person or virtually. All participants opted to complete this visit virtually and so the consultation visit was modified to be exclusively conducted virtually.

Abbreviations

ASD	Autism spectrum disorder(s)
ABC-2	Aberrant Behavior Checklist, 2nd Edition
ACC	Active control condition
ACT	Acceptance and commitment therapy
ADOS-2	Autism Diagnostic Observation Schedule-2nd Edition
AIMS	Achieving Independence and Mastery in School
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
BRIEF-2	Behavioral Rating Inventory of Executive Functioning, 2nd Edition
CBT	Cognitive behavioral therapy
CCHMC	Cincinnati Children's Hospital Medical Center
CEC	Community Engagement Core
CGI-I	Clinician Global Impressions-Improvement
CGI-S	Clinician Global Impressions-Severity
COSS	Children's Organizational Skills Scale
CRF	Case Report Form
CRS	Caregiver Readiness and Satisfaction Survey
DoD	Department of Defense
DPD	Daily phone diary
DSM-5	Diagnostic and Statistical Manual, Fifth Edition
DSMB	Data and Safety Monitoring Board
EASE	Emotional Awareness and Skills Enhancement
ECG	Electrocardiogram
ED	Emotion dysregulation
EDI-D	Emotion Dysregulation Inventory– Dysphoria subscale
EDI-R	Emotion Dysregulation Inventory– Reactivity subscale
ERST	Emotion Regulation Skills Test
FSIQ	Full-scale intelligence quotient
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
HRV	Heart rate variability
ICC	Intraclass correlation coefficient
IQ	Intelligence quotient
MAAS	Mindfulness Attention and Awareness Scale
NDA	National Institute of Mental Health Data Archive
NDD	Neurodevelopmental disability
NIH	National Institutes of Health
NVIQ	Nonverbal intelligence quotient
PI	Principal Investigator
PIRC	Psychiatric Intake Response Center
PRL	Probabilistic Reversal Learning
PROMIS	Patient-Reported Outcomes Measurement Information System
PSEaS	Autism-Specific Parenting Self-Efficacy Scale
PSI-4	Parenting Stress Index, 4th Edition
RCT	Randomized controlled trial
REDCap	Research Electronic Data Capture
RT	Regulating Together
SAS: OR	Secret Agent Society: Operation Regulation
SES	Socioeconomic status
SSL	Secure Sockets Layer
STAMP	Stress and Anger Management Plan
TCI	Therapeutic Crisis Intervention
TPOCS	Therapy Process Observation Coding System
WASI-II	Weschler Abbreviated Scale of Intelligence, Second Edition

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40359-025-02737-6.

Supplementary Material 1

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Author contributions
RS, WSM, and LT drafted the manuscript. RS, KB, LS, SW, and PSH contributed to the original grant and IRB protocol. PSH conceptualized and drafted statistical analyses and randomization procedures. RS, LS, and JR authored the Regulating Together intervention. LS conceptualized, designed, and drafted probabilistic reversal learning procedures. DR conceptualized, designed, and drafted heart rate variability procedures. KB, SS, and SK assisted with protocol development changes over time. SWW conceptualized, designed, and drafted video coding procedures. KB and RS conceptualized, designed, and drafted qualitative research procedures. All authors reviewed and approved the final version of the manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study protocol has been approved by the Cincinnati Children's Hospital Medical Center (CCHMC) Institutional Review Board (IRB00000231). Full consent/assent procedures are reported under the Ethical Approval subheading.

Consent for publication
Not applicable.

Competing interests
RS, LS, and JR are co-creators of Regulating Together and receive compensation for trainings.

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References

1. Eisenberg N, Spinrad TL. Emotion-related regulation: sharpening the definition. Child Dev. 2004;75(2):334–9.
2. Mazefsky CA, Herrington J, Siegel M, Scarpa A, Maddox BB, Scahill L, et al. The role of emotion regulation in autism spectrum disorder. J Am Acad Child Adolesc Psychiatry. 2013;52(7):679–88.
3. White SW, Mazefsky CA, Dichter GS, Chiu PH, Richey JA, Ollendick TH. Social-cognitive, physiological, and neural mechanisms underlying emotion

regulation impairments: Understanding anxiety in autism spectrum disorder. Int J Dev Neurosci. 2014;39:22–36.
4. Rieffe C, Oosterveld P, Terwogt MM, Mootz S, van Leeuwen E, Stockmann L. Emotion regulation and internalizing symptoms in children with autism spectrum disorders. Autism. 2011;15(6):655–70.
5. Pouw LBC, Rieffe C, Stockmann L, Gadow KD. The link between emotion regulation, social functioning, and depression in boys with ASD. Res Autism Spectr Disorders. 2013;7(4):549–56.
6. Ting V, Weiss JA. Emotion regulation and parent Co-Regulation in children with autism spectrum disorder. J Autism Dev Disord. 2017;47(3):680–9.
7. Samson AC, Hardan AY, Lee IA, Phillips JM, Gross JJ. Maladaptive behavior in autism spectrum disorder: the role of emotion experience and emotion regulation. J Autism Dev Disord. 2015;45(11):3424–32.
8. Mayes SD, Kokotovich C, Mathiowetz C, Baweja R, Calhoun SL, Waxmonsky J. Disruptive mood dysregulation disorder symptoms by age in autism, ADHD, and general population samples. J Mental Health Res Intellect Disabil. 2017;10(4):345–59.
9. Simonoff E, Pickles A, Charman T, Chandler S, Loucas T, Baird G. Psychiatric disorders in children with autism spectrum disorders: prevalence, comorbidity, and associated factors in a population-derived sample. J Am Acad Child Adolesc Psychiatry. 2008;47(8):921–9.
10. Leyfer OT, Folstein SE, Bacalman S, Davis NO, Dinh E, Morgan J, et al. Comorbid psychiatric disorders in children with autism: interview development and rates of disorders. J Autism Dev Disord. 2006;36(7):849–61.
11. Kerns CM, Rast JE, Shattuck PT. Prevalence and correlates of Caregiver-Reported mental health conditions in youth with autism spectrum disorder in the united States. J Clin Psychiatry. 2020;82(1).
12. Kim JA, Szatmari P, Bryson SE, Streiner DL, Wilson FJ. The prevalence of anxiety and mood problems among children with autism and asperger syndrome. Autism. 2000;4(2):117–32.
13. Lainhart JE. Psychiatric problems in individuals with autism, their parents and siblings. Int Rev Psychiatry. 1999;11(4):278–98.
14. Mazzone L, Ruta L, Reale L. Psychiatric comorbidities in asperger syndrome and high functioning autism: diagnostic challenges. Ann Gen Psychiatry. 2012;11(1):16.
15. Mazefsky CA, White SW. Emotion regulation: concepts & practice in autism spectrum disorder. Child Adolesc Psychiatr Clin N Am. 2014;23(1):15–24.
16. Nader-Grosbois N, Mazzone S. Emotion regulation, personality and social adjustment in children with autism spectrum disorders. Psychology. 2014;05(15):1750–67.
17. Cai RY, Richdale AL, Uljarevic M, Dissanayake C, Samson AC. Emotion regulation in autism spectrum disorder: where we are and where we need to go. Autism Res. 2018;11(7):962–78.
18. Goldsmith SF, Kelley E. Associations between emotion regulation and social impairment in children and adolescents with autism spectrum disorder. J Autism Dev Disord. 2018;48(6):2164–73.
19. Conner CM, Golt J, Righi G, Shaffer R, Siegel M, Mazefsky CA. A comparative study of suicidality and its association with emotion regulation impairment in large ASD and US Census-Matched samples. J Autism Dev Disord. 2020;50(10):3545–60.
20. Stringer D, Kent R, Briskman J, Lukito S, Charman T, Baird G, et al. Trajectories of emotional and behavioral problems from childhood to early adult life. Autism. 2020;24(4):1011–24.
21. White SW, Roberson-Nay R. Anxiety, social deficits, and loneliness in youth with autism spectrum disorders. J Autism Dev Disord. 2009;39(7):1006–13.
22. Gotham K, Brunwasser SM, Lord C. Depressive and anxiety symptom trajectories from school age through young adulthood in samples with autism spectrum disorder and developmental delay. J Am Acad Child Adolesc Psychiatry. 2015;54(5):369–76. e3.
23. Righi G, Benevides J, Mazefsky C, Siegel M, Sheinkopf SJ, Morrow EM, et al. Predictors of inpatient psychiatric hospitalization for children and adolescents with autism spectrum disorder. J Autism Dev Disord. 2018;48(11):3647–57.
24. Siegel M. The severe end of the spectrum: insights and opportunities from the autism inpatient collection (AIC). J Autism Dev Disord. 2018;48(11):3641–6.
25. Leigh JP, Du J. Brief report: forecasting the economic burden of autism in 2015 and 2025 in the united States. J Autism Dev Disord. 2015;45(12):4135–9.
26. Trosper SE, Buzzella BA, Bennett SM, Ehrenreich JT. Emotion regulation in youth with emotional disorders: implications for a unified treatment approach. Clin Child Fam Psychol Rev. 2009;12(3):234–54.
27. Lynch SJ, Sunderland M, Newton NC, Chapman C. A systematic review of transdiagnostic risk and protective factors for general and specific psychopathology in young people. Clin Psychol Rev. 2021;87:102036.
28. Chad-Friedman E, Galano MM, Lemay EP, Olino TM, Klein DN, Dougherty LR. Parsing between- and within-person effects: longitudinal associations between irritability and internalizing and externalizing problems from early childhood through adolescence. Dev Psychopathol. 2023;35(3):1371–81.
29. Morelen D, Jacob ML, Suveg C, Jones A, Thomassin K. Family emotion expressivity, emotion regulation, and the link to psychopathology: examination across race. Br J Psychol. 2013;104(2):149–66.
30. Willner CJ, Gatzke-Kopp LM, Bray BC. The dynamics of internalizing and externalizing comorbidity across the early school years. Dev Psychopathol. 2016;28(4pt1):1033–52.
31. Essau CA, de la Torre-Luque A. Comorbidity between internalising and externalising disorders among adolescents: symptom connectivity features and psychosocial outcome. Child Psychiatry Hum Dev. 2023;54(2):493–507.
32. Dudley R, Kuyken W, Padesky CA. Disorder specific and trans-diagnostic case conceptualisation. Clin Psychol Rev. 2011;31(2):213–24.
33. Lerner MD, White SW, McPartland JC. Mechanisms of change in psychosocial interventions for autism spectrum disorders. Dialogues Clin Neurosci. 2012;14(3):307–18.
34. Weiss JA. Transdiagnostic case conceptualization of emotional problems in youth with ASD: an emotion regulation approach. Clin Psychol (New York). 2014;21(4):331–50.
35. White SW, Ollendick T, Albano AM, Oswald D, Johnson C, Southam-Gerow MA, et al. Randomized controlled trial: multimodal anxiety and social skill intervention for adolescents with autism spectrum disorder. J Autism Dev Disord. 2013;43(2):382–94.
36. Wood JJ, Drahota A, Sze K, Har K, Chiu A, Langer DA. Cognitive behavioral therapy for anxiety in children with autism spectrum disorders: a randomized, controlled trial. J Child Psychol Psychiatry. 2009;50(3):224–34.
37. Sofronoff K, Attwood T, Hinton S. A randomised controlled trial of a CBT intervention for anxiety in children with asperger syndrome. J Child Psychol Psychiatry. 2005;46(11):1152–60.
38. Reaven J, Blakeley-Smith A, Culhane-Shelburne K, Hepburn S. Group cognitive behavior therapy for children with high-functioning autism spectrum disorders and anxiety: a randomized trial. J Child Psychol Psychiatry. 2012;53(4):410–9.
39. Beck KB, Conner CM, Breitenfeldt KE, Northrup JB, White SW, Mazefsky CA. Assessment and treatment of emotion regulation impairment in autism spectrum disorder across the life span: current state of the science and future directions. Child Adolesc Psychiatr Clin N Am. 2020;29(3):527–42.
40. Neacsiu AD, Eberle JW, Kramer R, Wiesmann T, Linehan MM. Dialectical behavior therapy skills for transdiagnostic emotion dysregulation: a pilot randomized controlled trial. Behav Res Ther. 2014;59:40–51.
41. Queen AH, Barlow DH, Ehrenreich-May J. The trajectories of adolescent anxiety and depressive symptoms over the course of a transdiagnostic treatment. J Anxiety Disord. 2014;28(6):511–21.
42. Sakiris N, Berle D. A systematic review and meta-analysis of the unified protocol as a transdiagnostic emotion regulation based intervention. Clin Psychol Rev. 2019;72:101751.
43. Cisler JM, Olatunji BO, Feldner MT, Forsyth JP. Emotion regulation and the anxiety disorders: an integrative review. J Psychopathol Behav Assess. 2010;32(1):68–82.
44. Afshari A, Neshat-Doost HT, Maracy MR, Ahmady MK, Amiri S. The effective comparison between emotion-focused cognitive behavioral group therapy and cognitive behavioral group therapy in children with separation anxiety disorder. J Res Med Sci. 2014;19(3):221–7.
45. Corstorphine E. Cognitive-Emotional-Behavioural therapy for the eating disorders: working with beliefs about emotions. Eur Eat Disorders Rev. 2006;14(6):448–61.
46. Kumar S, Feldman G, Hayes A. Changes in mindfulness and emotion regulation in an Exposure-Based cognitive therapy for depression. Cogn Therapy Res. 2008;32(6):734–44.
47. Derella OJ, Johnston OG, Loeber R, Burke JD. CBT-enhanced emotion regulation as a mechanism of improvement for childhood irritability. J Clin Child Adolesc Psychol. 2019;48(sup1):S146–54.
48. Mennin DS. Emotion regulation therapy: an integrative approach to Treatment-Resistant anxiety disorders. J Contemp Psychotherapy: Cut Edge Mod Developments Psychother. 2006;36(2):95–105.

49. Koerner K, Linehan MM. Research on dialectical behavior therapy for patients with borderline personality disorder. Psychiatr Clin North Am. 2000;23(1):151–67.
50. Adams D, Young K. A systematic review of the perceived barriers and facilitators to accessing psychological treatment for mental health problems in individuals on the autism spectrum. Rev J Autism Dev Disorders. 2021;8(4):436–53.
51. Conner CM, White SW, Beck KB, Golt J, Smith IC, Mazefsky CA. Improving emotion regulation ability in autism: the emotional awareness and skills enhancement (EASE) program. Autism. 2019;23(5):1273–87.
52. Factor RS, Swain DM, Antezana L, Muskett A, Gatto AJ, Radtke SR, et al. Teaching emotion regulation to children with autism spectrum disorder: outcomes of the stress and anger management program (STAMP). Bull Menninger Clin. 2019;83(3):235–58.
53. Weiss JA, Thomson K, Burnham Riosa P, Albaum C, Chan V, Maughan A, et al. A randomized waitlist-controlled trial of cognitive behavior therapy to improve emotion regulation in children with autism. J Child Psychol Psychiatry. 2018;59(11):1180–91.
54. Gill D, Warburton W, Simes D, Sweller N. Group therapy for emotional dysregulation: treatment for adolescents and their parents. Child Adolesc Social Work J. 2018;35(2):169–80.
55. Hong ER, Neely L, Gerow S, Gann C. The effect of caregiver-delivered social-communication interventions on skill generalization and maintenance in ASD. Res Dev Disabil. 2018;74:57–71.
56. de Marchena AB, Eigsti IM, Yerys BE. Brief report: generalization weaknesses in verbally fluent children and adolescents with autism spectrum disorder. J Autism Dev Disord. 2015;45(10):3370–6.
57. Beck KB, Northrup JB, Breitenfeldt KE, Porton S, Day TN, MacKenzie KT, et al. Stakeholder informed development of the emotion awareness and skills enhancement team-based program (EASE-Teams). Autism. 2022;26(3):586–600.
58. Shaffer RC, Wink LK, Ruberg J, Pittenger A, Adams R, Sorter M, et al. Emotion regulation intensive outpatient programming: development, feasibility, and acceptability. J Autism Dev Disord. 2019;49(2):495–508.
59. Shaffer RC, Schmitt LM, Reisinger DL, Coffman M, Horn P, Goodwin MS, et al. Regulating together: emotion dysregulation group treatment for ASD youth and their caregivers. J Autism Dev Disord. 2023;53(5):1942–62.
60. Wong C, Odom SL, Hume KA, Cox AW, Fettig A, Kucharczyk S, et al. Evidence-Based practices for children, youth, and young adults with autism spectrum disorder: A comprehensive review. J Autism Dev Disord. 2015;45(7):1951–66.
61. Smith KA, Gehricke JG, Iadarola S, Wolfe A, Kuhlthau KA. Disparities in service use among children with autism: A systematic review. Pediatrics. 2020;145(Suppl 1):S35–46.
62. Tamm L, Zoromski AK, Kneeskern EE, Patel M, Lacey HM, Vaughn AJ, et al. Achieving independence and mastery in school: an open trial in the outpatient setting. J Autism Dev Disord. 2021;51(5):1705–18.
63. Lord C, Rutter M, DiLavore PC, Risi S, Gotham K, Bishop S. Autism diagnostic observation schedule, second edition (ADOS-2). Torrance, CA: Western Psychological Services; 2012.
64. Wechsler D. Wechsler abbreviated scale of Intelligence–Second edition (WASI-II). San Antonio, TX: NCS Pearson; 2011.
65. Mazefsky CA, Day TN, Siegel M, White SW, Yu L, Pilkonis PA, et al. Development of the emotion dysregulation inventory: A PROMIS(R)ing method for creating sensitive and unbiased questionnaires for autism spectrum disorder. J Autism Dev Disord. 2018;48(11):3736–46.
66. Sparrow SS, Cicchetti DV, Saulnier CA. Vineland Adaptive Behavior Scales, Third Edition. Bloomington, MN: NCS Pearson, Inc.; 2016.
67. Guy W. ECDEU Assessment Manual for Psychopharmacology. Rockville, MD: US Department of Heath, Education, and Welfare Public Health Service Alcohol, Drug Abuse, and Mental Health Administration; 1976.
68. Dunn-Rankin P, Shimizu M, King FJ. Reward preference patterns in elementary school children. In: Rosenblith JF, Allinsmith W, Williams J, editors. Readings in educational psychology: causes of behavior. Boston, MA: Allyn and Bacon, Inc.; 1973.
69. Mazefsky CA, Yu L, White SW, Siegel M, Pilkonis PA. The emotion dysregulation inventory: psychometric properties and item response theory calibration in an autism spectrum disorder sample. Autism Res. 2018;11(6):928–41.
70. Mazefsky CA, Yu L, Pilkonis PA. Psychometric properties of the emotion dysregulation inventory in a nationally representative sample of youth. J Clin Child Adolesc Psychol. 2021;50(5):596–608.
71. Modi AC, Marciel KK, Slater SK, Drotar D, Quittner AL. The influence of parental supervision on medical adherence in adolescents with cystic fibrosis: developmental shifts from pre to late adolescence. Children's Health Care. 2008;37(1):78–82.
72. Quittner AL, Modi AC, Lemanek KL, Ievers-Landis CE, Rapoff MA. Evidence-based assessment of adherence to medical treatments in pediatric psychology. J Pediatr Psychol. 2008;33(9):916–36. discussion 37–8.
73. Reisinger DL, Goodwin MS, Horn PS, Schmitt LM, Coffman MC, Shaffer RC. Examining the feasibility and utility of heart rate variability on intervention outcomes targeting emotion regulation in autism: a brief report. Sci Rep. 2024;14(1):15409.
74. Schmitt LM, Sweeney JA, Erickson CA, Shaffer R. Brief report: feasibility of the probabilistic reversal learning task as an outcome measure in an intervention trial for individuals with autism spectrum disorder. J Autism Dev Disord. 2022;52(9):4191–9.
75. Abikoff H, Gallagher R. Children's organizational skills scales manual. North Tonawanda, NY: Multi-Health Systems; 2009.
76. Brown KW, Ryan RM. The benefits of being present: mindfulness and its role in psychological well-being. J Pers Soc Psychol. 2003;84(4):822–48.
77. Lawlor MS, Schonert-Reichl KA, Gadermann AM, Zumbo BD. A validation study of the mindful attention awareness scale adapted for children. Mindfulness. 2014;5(6):730–41.
78. Gioia GA, Isquith PK, Guy SC, Kenworthy L. Behavior Rating Inventory of Executive Function®, Second Edition (BRIEF®2). Lutz, FL: PAR Inc.; 2015.
79. Aman MG, Singh NN. Aberrant behavior checklist manual. 2nd ed. East Aurora, NY: Slosson Educational; 2017.
80. Kaat AJ, Lecavalier L, Aman MG. Validity of the aberrant behavior checklist in children with autism spectrum disorder. J Autism Dev Disord. 2014;44(5):1103–16.
81. Cella D, Yount S, Rothrock N, Gershon R, Cook K, Reeve B, et al. The Patient-Reported outcomes measurement information system (PROMIS): progress of an NIH roadmap cooperative group during its first two years. Med Care. 2007;45(5 Suppl 1):S3–11.
82. Irwin DE, Stucky B, Langer MM, Thissen D, Dewitt EM, Lai JS, et al. An item response analysis of the pediatric PROMIS anxiety and depressive symptoms scales. Qual Life Res. 2010;19(4):595–607.
83. Strang JF, Anthony LG, Yerys BE, Hardy KK, Wallace GL, Armour AC, et al. The flexibility scale: development and preliminary validation of a cognitive flexibility measure in children with autism spectrum disorders. J Autism Dev Disord. 2017;47(8):2502–18.
84. D'Cruz AM, Ragozzino ME, Mosconi MW, Shrestha S, Cook EH, Sweeney JA. Reduced behavioral flexibility in autism spectrum disorders. Neuropsychology. 2013;27(2):152–60.
85. Schmitt LM, Bojanek E, White SP, Ragozzino ME, Cook EH, Sweeney JA, et al. Familiality of behavioral flexibility and response Inhibition deficits in autism spectrum disorder (ASD). Mol Autism. 2019;10:47.
86. Kurzrok J, McBride E, Grossman RB. Autism-specific parenting self-efficacy: an examination of the role of parent-reported intervention involvement, satisfaction with intervention-related training, and caregiver burden. Autism. 2021;25(5):1395–408.
87. Abidin RR. Parenting stress index: fourth edition. Lutz, FL: PAR, Inc.; 2012.
88. McLeod BD, Weisz JR. The therapy process observational coding system-alliance scale: measure characteristics and prediction of outcome in usual clinical practice. J Consult Clin Psychol. 2005;73(2):323–33.
89. Lerner MD, McLeod BD, Mikami AY. Preliminary evaluation of an observational measure of group cohesion for group psychotherapy. J Clin Psychol. 2013;69(3):191–208.
90. Beidel DC, Turner SM, Taylor-Ferreira JC. Teaching study skills and test-taking strategies to elementary school students. Testbusters Program Behav Modif. 1999;23(4):630–46.

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