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ORIGINAL PAPER

Stepped-Care Cognitive Behavioral Therapy in Children on the Autism Spectrum with Co-occurring Anxiety

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Abstract
This trial examined stepped-care cognitive-behavioral treatment (CBT) among 96 autistic youth with co-occurring anxiety. Step 1 included an open trial of parent-led, therapist-guided bibliotherapy. Step 2 was family-based CBT for those who did not respond to Step 1 or maintenance for those who did. Eighteen participants (28%) who completed Step 1 responded. Responders reported significantly lower pre-treatment anxiety, internalizing symptoms, and functional impairment than non-responders. After Steps 1 and 2, 80% of completers (55% intent-to-treat) were responders. Anxiety, impairment, and ASD-related impairments significantly improved. Youth in maintenance experienced faster improvement through post-treatment, though there were no group differences at 3-month-follow-up. A stepped approach may help some individuals in Step 1, particularly those who are less anxious.

Keywords Autism spectrum disorder · Anxiety · Obsessive–compulsive disorder · Cognitive behavioral therapy · Treatment · Children

Anxiety disorders are frequent and impairing among autistic individuals, affecting approximately 50% of children and adolescents (Vasa & Mazurek, 2015). Anxiety confers significant functional impairment, and symptoms follow a worsening trajectory into adolescence and young adulthood without adequate treatment (Gotham et al., 2015; Kuusikko et al., 2008). Cognitive behavioral therapy (CBT) tailored for autistic youth with co-occurring anxiety is a well-established evidence-based treatment. CBT has demonstrated superiority to waitlist and usual care controls (Reaven et al., 2012; Sofronoff et al., 2005; Storch et al., 2013, 2015; Wood et al., 2009, 2015, 2020), as well as standard-care CBT (Wood et al., 2020). Although there are several different empirically-supported CBT protocols, each shares similar components (i.e., exposure, cognitive therapy), which are delivered in a therapist-led "full-treatment" package in which 12–16 sessions are provided sequentially.

While the practice of treating anxious autistic youth has witnessed meaningful progress, barriers remain to accessing care. These include limited number of trained providers skilled in working with youth on the autism spectrum, clinician reluctance/comfort to work with autistic youth, family stigma and distrust of the mental health system, and financial and logistical barriers (e.g., cost associated with treatment, transportation, child care, work demands) (Bringewatt & Gershoff, 2010; Reardon et al., 2017). Parents also often desire to independently solve their child's problem (Thurston & Phares, 2008), which may limit treatment-seeking efforts.

Stepped-care treatment protocols hold promise in reducing treatment barriers. Stepped-care models provide a

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lower-intensity, first step of treatment that takes less time and costs less, with the goal of helping a meaningful proportion of patients while stepping up individuals who do not benefit from lower intensity interventions to more intensive services (Salloum et al., 2014). Examples of first-step interventions include bibliotherapy, shortened treatment durations, and parent-led approaches. Engaging parents in a co-therapist or lead role is particularly promising, as this approach may increase service access by reducing the need for dedicated therapist time (Kazdin, 2019). An important component of stepped-care interventions involves pre-established monitoring systems to assess symptom status and subsequent treatment needs (Bower & Gilbody, 2005).

Building on positive findings among non-autistic adults with anxiety and/or obsessive–compulsive disorder (OCD) (Nordgreen et al., 2016; Tolin et al., 2011), stepped-care CBT approaches have been tested in several trials of youth with anxiety who are not autistic. There are no identifiable studies of stepped-care treatment for anxiety in autistic individuals. Rapee et al. (2017) compared standard CBT versus a stepped model involving parent-led, therapist-assisted CBT for childhood anxiety followed by standard CBT and then individually tailored CBT. Overall, 41% of youth responded to step one, 38.8% responded to steps one and two. Stepped-care treatment and single-treatment CBT were similar in treatment efficacy, and stepped-care treatment presented far less time cost to therapists involved in treatment. Additionally, several pilot studies have been conducted in youth with PTSD, finding that a stepped-care version of trauma focused CBT (SC-TF-CBT) demonstrated comparable outcomes to TF-CBT in posttraumatic stress symptoms, and internalizing symptoms and externalizing symptoms over time (Salloum et al., 2014, 2015). In a large, randomized trial, 183 youth were randomly assigned to either SC-TF-CBT or standard TF-CBT. A total of 70.5% of completers (47.3% for intent to treat (ITT)) responded to Step 1 treatment. SC-TF-CBT was non-inferior to TF-CBT, with approximately 38.4–53.7% lower costs associated with SC-TF-CBT (Salloum et al., 2022a, 2022b).

There have been few studies examining predictors of stepped-care treatment outcomes. Among adults, Haug et al. (2015) found that higher impairment, lower social functioning, and depression comorbidity were associated with attenuated outcome to stepped-care CBT for panic and social anxiety disorders (Haug et al., 2015). Thirlwall et al. (2017) found that guided parent-delivered CBT used in low intensity phase of stepped-care CBT treatments yielded positive outcomes for children with separation anxiety disorder and social anxiety disorder. Participants with these disorders and older youth had greater chance for improvement at post-treatment. While not a stepped-care model, Storch et al. (2021) examined full courses of personalized, adapted CBT against standard CBT for children with anxiety and ASD and found that externalizing or internalizing symptoms predicted poorer treatment outcomes overall, which may also extend to stepped models for autistic youth with co-occurring anxiety.

The current study extends past studies of stepped-care treatment in childhood anxiety and PTSD to youth on the autism spectrum with co-occurring anxiety. There were three primary study aims. First, we sought to examine the proportion of youth who responded to Step One parent-led, therapist-assisted CBT. Based on findings in childhood anxiety and PTSD, we predicted that approximately 35% of youth would respond following Step One. Second, we examined the effectiveness of stepped-care CBT (e.g., starting with Step One parent-led, therapist-assisted treatment and then either maintenance or Step Two therapist-directed CBT). Given the second-stage treatments provided (maintenance or family-based CBT), we predicted that youth in stepped-care CBT would demonstrate significant improvements in: (a) anxiety symptom severity (primary outcome), functional impairment, internalizing behaviors, and global improvement; and (b) parents would report high acceptability and satisfaction levels. Third, we examined potential predictors of response to the lower intensity, Step One treatment. We expected that higher baseline child anxiety, impairment, externalizing symptoms and caregiver depressive symptoms would be associated with attenuated Step One response.

Method

Participants

Ninety-six children (84.4% male, 15.6% female; *M* age = 10.39 years, *SD* 2.86 years) were enrolled between January 2019 and November 2020 (intended sample was 120; See Table 1 and Fig. 1). Inclusion criteria required that the child: (a) be between 4 and 14 years of age at enrollment; (b) have an established diagnosis of ASD already made by a prior assessment as well as a baseline score of ≥ 65 on the Social Responsiveness Scale, 2nd Edition (Constantino & Gruber, 2012); (c) have clinically significant symptoms of anxiety or OCD, as indicated by a clinical severity rating ≥ 4 for an anxiety/OCD diagnosis on the Anxiety Disorders Interview Schedule UC, Child/Parent Version (ADIS-IV-C/P; Silverman & Albano, 1996) with Autism Spectrum Addendum (ASA) (Kerns et al., 2017) and a score > 12 on the Pediatric Anxiety Rating Scale (PARS) (RUPP, 2002); (d) have anxiety and/or OCD indicated as the primary, non-ASD presenting problem as determined by the independent evaluator; (e) demonstrate both full scale and verbal comprehension IQ ≥ 70, as indicated by the Differential Ability Scales-II (DAS-II; Beran, 2007) or Wechsler Abbreviated Scale of Intelligence-Second Edition (WASI-II; Weschler, 2011); and (f) agree to participate in treatment, along with

Table 1 Demographics table and baseline clinical characteristics

	Full sample $n=76$	Step 1 responders $n=18$	Step 1 Non-responders $n=46$	Difference between subsamples[a]	Effect size [95% CI][b]
Primary diagnosis, N (%)				χ^2 (1) = 5.57	
Specific phobia	15 (20%)	5 (28%)	4 (9%)		*OR* 4.03 [0.94, 17.29]
Social anxiety	12 (16%)	3 (17%)	7 (15%)		*OR* 1.11 [0.25, 4.88]
Separation anxiety	21 (28%)	3 (17%)	16 (35%)		*OR* 0.38 [0.094, 1.49]
Generalized anxiety disorder	16 (21%)	5 (28%)	10 (22%)		*OR* 1.38 [0.40, 4.82]
Selective mutism	0 (0%)	0 (0%)	0 (0%)		*N/A*
Obsessive–compulsive disorder	4 (5%)	0 (0%)	4 (9%)		*N/A*
Other specified anxiety disorder	8 (11%)	2 (11%)	5 (11%)		*OR* 1.03 [0.18, 5.83]
Age, M (SD)				t (62) = 1.09	*OR* .30 [−.25, .85]
Child gender, N (%)				χ^2 (1) = 0.071	*OR* 0.82 [0.78, 1.80]
Male	63 (83%)	15 (83.3%)	37 (80.4%)		
Female	13 (17%)	3 (16.7%)	9 (19.6%)		
Race				χ^2 (1) = 0.10[c]	*OR* 1.22[c] [0.55, 2.72]
White	57 (75%)	13 (72.2%)	35 (76.1%)		
Black or African American	6 (7.9%)	1 (5.6%)	4 (8.7%)		
Asian	5 (6.6%)	0 (0%)	5 (10.9%)		
American Indian or Alaskan Native	1 (1.3%)	1 (5.6%)	0 (0%)		
Mixed race	6 (7.9%)	3 (16.7%)	2 (4.3%)		
Other	1 (1.3%)	0 (0%)	0 (0%)		
Ethnicity				χ^2 (1) = 0.071	*OR* 1.14 [0.51, 2.58]
Hispanic or Latino	26 (34.2%)	6 (33.3%)	14 (30.4%)		
Not Hispanic or Latino	50 (65.8%)	12 (66.7%)	32 (69.6%)		
Mother's age	40.21 ± 4.71 years				
Father's age	41.59 ± 9.64 years				
Mother education				χ^2 (2) = 0.94	
Associate's degree, high school diploma, some college, or vocational school	25 (32.8%)	3 (16.7%)	14 (28.3%)		*OR* 0.51 [0.12, 2.05]
Bachelor's degree	27 (35.5%)	8 (44.4%)	17 (37%)		*OR* 0.73 [0.25, 2.21]
Graduate degree	24 (31.6%)	7 (38.9%)	16 (34.8%)		*OR* 1.19 [0.39, 3.67]
Father education				χ^2 (2) = 5.96	
Associate's degree, high school diploma, some college, or vocational school	30 (39.4%)	4 (22.3%)	18 (39.1%)		*OR* 0.40 [0.11, 1.41]
Bachelor's degree	26 (34.2%)	11 (61.1%)	12 (26.1%)		*OR* 0.25 [0.078, 0.78]
Graduate degree	16 (21.1%)	3 (16.7%)	3 (6.5%)		*OR* 0.46 [0.11, 1.87]

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

[a]Tested with χ^2 for categorical variables to test proportion differences and t tests for continuous variables

[b]*OR*s in the education comparisons were calculated by comparing the odds of being a Step 1 responder in the identified race/educational group vs. the other groups (e.g., the odds of participants with mothers with a bachelor's degree responding to Step 1 vs. the odds of participants with another level of education responding to Step 1). *ORs* in the race category were calculated as White vs. non-White because of the small number of non-White participants, and thus limited statistical power to compare to other groups individually

[c]Refers to White vs. non-White comparison because of the limited sample identifying as non-White

one parent/guardian. The IQ ≥ 70 criterion was used given the verbal nature of the CBT protocols used, especially for autistic youth 7 and older.

Exclusion criteria included: (1) lifetime DSM-5 diagnoses of bipolar disorder, psychotic disorder, or intellectual disability; (2) active suicidal/homicidal ideation or self-injury requiring medical intervention; (3) the child receiving concurrent psychotherapy for anxiety; and (4) the child having initiated or changed dosage of psychiatric medication before enrollment in the study

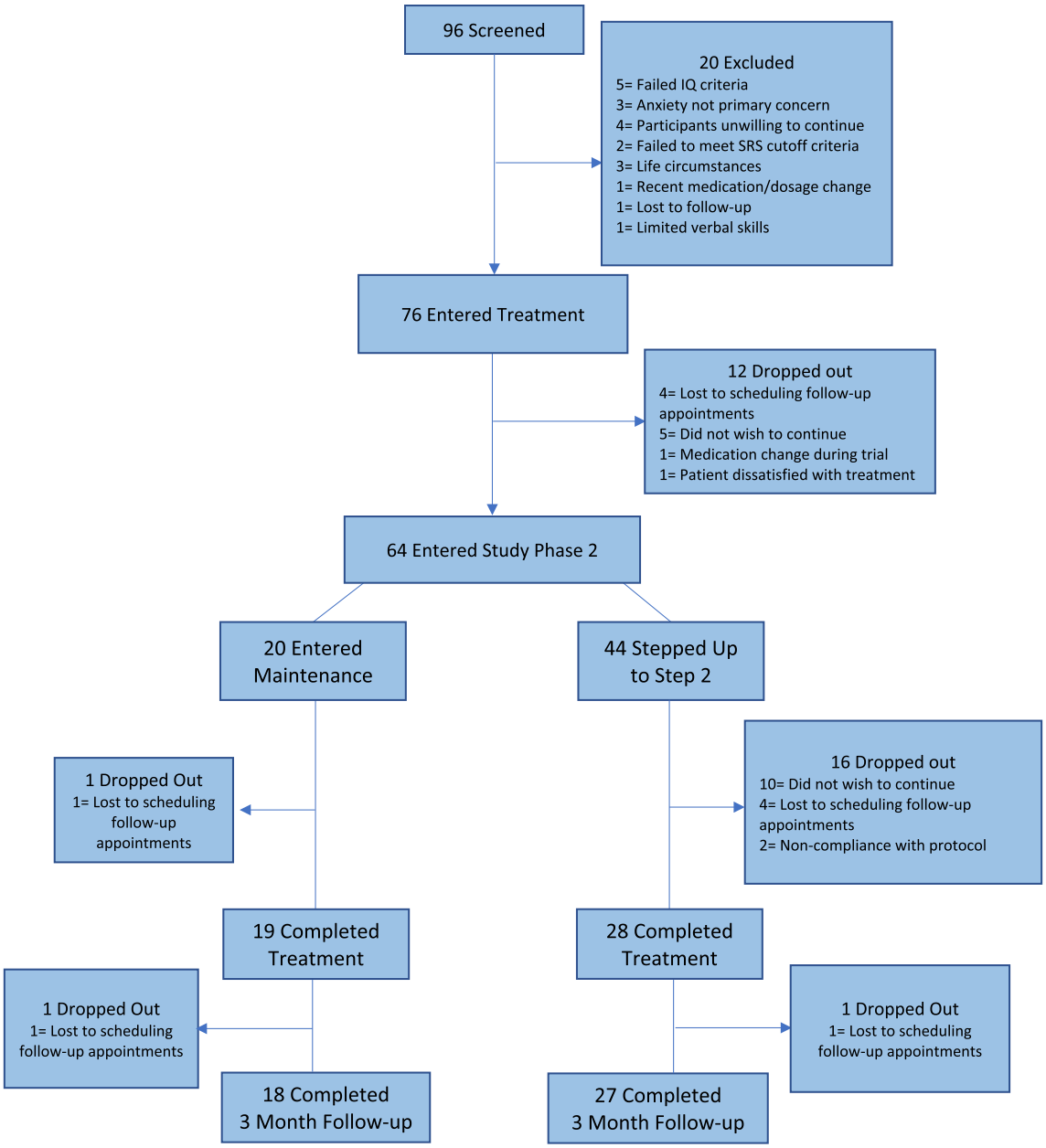

Fig. 1 Study Consort Diagram

(8 weeks for medication initiation; 4 weeks for change in antidepressant medication and 2 weeks for stimulant/benzodiazepine medication change).

Recruitment occurred through a variety of methods, including direct referrals from an ASD specialty center, social media, community engagement efforts (e.g., online outreach presentations, ASD database newsletters), and through the Tempus Dynamics SPARK research match database (Feliciano et al., 2018).

Procedures

This study was approved by the local Institutional Review Board. Study services were initially provided in-person at a clinical setting but were later shifted to telehealth services during the COVID-19 pandemic. Parents provided written consent for themselves and their child to participate in the study; when possible, child written or verbal assent was also obtained. Prior to start of treatment, participants completed

an initial 3- to 4-h baseline assessment to confirm eligibility criteria with an Independent Evaluator (IE). Additional IE-administered assessments occurred at mid-treatment, post-treatment, and 3-months after treatment. IEs were master's level or doctoral candidate clinicians who received extensive training prior to administering study measures, along with weekly supervision by a licensed psychologist (LB). Training consisted of a review of the relevant clinician measures, instructional didactics by the first author and developer of the ASA, and finally, co-rating several training cases to criterion (diagnostic agreement with an experienced clinician). Participants were compensated $40 for each assessment. Assessments were audio-recorded for quality assurance purposes.

Measures

Anxiety Disorders Interview Schedule-IV, Child/Parent Version with the Autism Addendum (ADIS-C/P/ASA)

The Anxiety Disorders Interview Schedule IV, C/P Version (ADIS-IV-C/P; Silverman & Albano, 1996) with Autism Spectrum Addendum (ASA) (Kerns et al., 2017) is a semi-structured diagnostic interview that assesses the presence and severity of DSM-IV anxiety disorders among children. The ASA provides a systematic approach for differentiating more ambiguous, ASD-related anxiety symptoms and traditional DSM-IV anxiety disorders. Parents are interviewed to determine diagnoses of child anxiety based on clinical severity ratings (CSR) on a scale of 0–8, with CSR scores ≥ 4 indicating clinical diagnoses and higher scores representing higher levels of clinical severity and impairment. The ADIS-C/P/ASA was administered at baseline and a CSR score ≥ 4 on one or more anxiety/OCD modules (including the ASA) was required to meet study inclusion criteria (with the exception of posttraumatic stress disorder). The ADIS-IV-C/P and ASA have demonstrated strong discriminant and interrater reliability (Hamblin et al., 2016; Kerns et al., 2017; Wood et al., 2002). It was administered at all assessment time points.

Pediatric Anxiety Rating Scale (PARS)

The Pediatric Anxiety Rating Scale (PARS; RUPP, 2002) is a clinician-rated instrument designed to assess anxiety-symptom severity in children. The measure consists of a 50-item symptom checklist and a 7-item severity rating scale assessing number of symptoms, frequency, symptom severity, avoidance, and interference. Checklist responses are obtained as Yes/No responses to queries about the presence of anxiety behaviors in the past 7 days; severity items are rated on a 6-point scale with responses ranging from *Minimal* (0) to *Extreme* (5). Questions are asked in an interview format, and the measure includes both parent and clinician responses. The PARS has demonstrated high inter-rater reliability, test–retest reliability, internal consistency, as well as convergent and divergent validity (Storch et al., 2012). This measure was completed at all assessment time points.

Child Behavior Checklist (CBCL/6–18)

The Child Behavior Checklist (CBCL; Achenbach, 1991) is a psychometrically-sound (Achenbach et al., 2008; Cohen et al., 1985) parent-rated questionnaire assessing internalizing and externalizing symptoms in children ages 6–18. The CBCL has robust psychometric properties in youth who are autistic (Hoffmann et al., 2016; Keefer et al., 2020; Pandolfi et al., 2012) and those who are not (Achenbach et al., 2008; Cohen et al., 1985; Nakamura et al., 2009; Seligman et al., 2004) The Internalizing and Externalizing subscales were used in this study (Baseline α for both subscales was .90). This measure was completed at all assessment time points.

Clinical Global Impression Scale-Severity and Improvement (CGI-Severity/-Improvement)

The CGI-Severity (Guy, 1976) is a 7-point, clinical-severity scale, ranging from *No illness* (0) to *Extremely severe symptoms*, *completely non-functional* (6). The CGI-Severity was rated by the IE at baseline, mid-treatment, post-treatment, and 3-month follow-up assessments. The CGI-Improvement (Guy, 1976) is a single-item, clinician-rated measure of overall diagnostic improvement and ranges from *very much worse* (1) to *very much improved* (7). In the current study, treatment responders were operationalized as scoring ≤ 2 (Mild Symptoms) on the CGI-Severity and 6 (much improved) or 7 (very much improved) on the CGI-Improvement. The CGI-Improvement was rated by the IE at mid-treatment, post-treatment, and 3-month follow-up assessments. The CGI-Severity was completed at all assessment time points.

Depressive, Anxiety, and Stress Symptoms-21 Item Version (DASS)

The DASS (Lovibond & Lovibond, 1995) is a 21-item Likert scale self-report questionnaire that assessed depressive symptoms, anxiety, and stress in caregivers. The DASS-21 is widely used and psychometrically validated (Tran et al., 2013). In this trial, the DASS-21 was used to evaluate whether caregiver emotional symptoms at baseline would be associated with an attenuated outcome to the lower intensity Step 1 treatment (DASS-Anxiety baseline $\alpha = .86$; DASS-Depression baseline $\alpha = .87$; DASS-Stress baseline $\alpha = .88$).

Social Responsiveness Scale-2 (SRS-2)

The SRS-2 (Constantino & Gruber, 2012) is a 65-item, parent-rated measure of social impairment and responsiveness. Responses are measured on a 4-point Likert-type scale, and questions address communicative abilities, repetitive behaviors, and behavioral and emotional affect that parents observe in their child. Scores ≥ 65 on the SRS-2 are suggestive of ASD (Cholemkery et al., 2014). The SRS-2 has demonstrated reliability and validity (Constantino & Gruber, 2012; Gergoudis et al., 2020; Kerns et al., 2017). This measure was completed at all assessment time points (Baseline α = 0.84).

Revised Child Anxiety and Depression Scale-Child and Parent Versions (RCADS-C/P)

The RCADS-C/P (Chorpita et al., 2000) are 47-item, parent and child-report questionnaires that assess anxiety and depressive symptoms in children. Items are rated on a 4-point scale, ranging from never to always, and assess the frequency of various anxiety and depressive symptoms. The RCADS-C/P have shown good internal consistency and convergent and discriminant validity (Chorpita et al., 2005; Ebesutani et al., 2010). Among autistic youth ($n = 67$), the RCADS demonstrated modest convergence with other anxiety assays, as well as fair associations with non-anxiety symptoms (attention problems) (Sterling et al., 2015). The RCADS-C/P were completed at all assessment time points, and the Anxiety scale was used as an outcome (RCADS-C baseline α = .93; RCADS-P baseline α = .91).

Child Sheehan Disability Scale Parent (CSDS-P)

The Child Sheehan Disability Scale Parent (CSDS-P; Whiteside, 2009) is a 6-item measure adapted from the Sheehan Disability Scale (Sheehan, 1986) designed to assess parent perception of interference and functional impairment within their child. The version used in this study omitted the item regarding anxiety interference with the child's social life, given that ratings would be conflated by ASD status. Items were oriented towards anxiety-related impairment and rated on an 11-point Likert type scale with responses ranging from 0 (not at all) to 10 (extremely). The scale is divided into two sections, with the first 3 measure questions assessing level of perceived child anxiety symptom interference with child functioning (in school, socially, and with family), and the second section assessing level of perceived anxiety symptom interference with parent functioning (at work, socially, and with family). The CSDS-P has demonstrated reliability and validity (Whiteside, 2009). Caregivers completed the CSDS at all assessment timepoints (Baseline α = 0.80).

Client Satisfaction Questionnaires (CSQ-8)

The Client Satisfaction Questionnaire (CSQ-8; Larsen et al., 1979) is an 8-item questionnaire designed to measure global satisfaction of clinical services received. Items assess quality of service, satisfaction with kind of service provided, needs met, likelihood to recommend service to a friend, help dealing with problems, amount of help provided and overall satisfaction (Matsubara et al., 2013). Participants rate items on a 4-point Likert scale ranging from 1 to 4, with 1 indicating the least satisfaction and 4 indicating the greatest satisfaction. This measure was completed at post-treatment by caregivers (α = .87).

Stepped-Care Design and Treatment

Step 1: Parent-Led, Therapist-Assisted CBT

Step 1 (low intensity) treatment consisted of parent-led, therapist-assisted CBT (PLTA-CBT) involving 4 treatment sessions over the course of 12 weeks. Participants were provided treatment materials, including a copy of the *Helping Your Anxious Child* (HYAC; Rapee et al., 2017) book, accompanying workbook, and training timeline. After receiving materials, participants were asked to begin work immediately and were scheduled for 45-min therapist-assisted sessions at the 3-, 5-, 7- and 9-week treatment timepoints. PLTA-CBT treatment followed HYAC and the accompanying workbook, and consisted of in vivo exposure and cognitive therapy modeled after a validated CBT protocol, namely *The Cool Kids Anxiety Program: Autism Spectrum Disorder Adaptation (Cool Kids ASD), 2nd Edition* (Lyneham et al., 2016). Weekly assignments of at home PLTA-CBT were assigned through chapters of the HYAC book, and therapist-assisted sessions were designed to discuss treatment strategies, deliver feedback, provide strategies to optimize treatment, and address behavioral or ASD-related challenges unique to each child. Participants completed an average of 3.4 sessions during this phase. All participants who completed 4 sessions or completed 12 weeks (N = 64) of treatment were considered to be Step 1 completers.

Therapists were masters-level or advanced doctoral candidate clinicians supervised by the first author who is a licensed clinical psychologist. Therapists underwent training in providing Step 1 care, and in the two CBT protocols: (1) *The Cool Kids Anxiety Program: Autism Spectrum Disorder Adaptation (Cool Kids ASD), 2nd Edition* (Lyneham et al., 2016) for children ages 6 and older; and (2) Exposure-Focused, Family-Based CBT for Youth with ASD

and Comorbid Anxiety (FET) for children ages 4–5 (Storch et al., 2020) (see additional details below). Therapists had prior experience working with autistic children.

Midterm Assessment

Participant response to Step 1 treatment was determined through an IE assessment lasting approximately 1 to 1.5 h. Measures were identical to those administered at baseline. Semi-structured clinical interviews were re-administered for all anxiety modules with CSR > 0. Participant response to Step 1 treatment was determined by ratings of clinical improvement and severity on the CGI-Improvement and CGI-Severity, respectively. Participants scoring ≤ 2 (Mild Symptoms) on the CGI-Severity and 6 (much improved) or 7 (very much improved) on the CGI-Improvement were considered to be responders to Step 1 treatment. All participants were notified of the decision to step up to Step 2 or the maintenance phase after a discussion with the research team.

Maintenance Phase

After completion of the midterm assessment, participants determined to be Step 1 responders entered into a maintenance phase for a 12-week period. During this phase, participants were asked to continue parent-led CBT at their own pace, without therapist assistance. Families were scheduled for a post-treatment assessment approximately 12 weeks after being notified of the decision to enter into maintenance phase. All participants were instructed to notify study personnel if they felt anxiety symptoms were worsening. Participants were considered to be completers of the maintenance phase of the study if they completed 12 weeks (N = 19).

Step 2: Therapist-Led CBT

Non-responders to Step 1 treatment were enrolled in therapist-led CBT for the second 12 weeks of treatment (Step 2, high-intensity phase). In this phase, parent–child dyads were scheduled for 10 therapist-led CBT sessions over the course of 12 weeks. Treatment protocols utilized in this condition were as follows: (1) *The Cool Kids Anxiety Program: Autism Spectrum Disorder Adaptation (Cool Kids ASD), 2nd Edition* (Lyneham et al., 2016) for children ages 6 and older; and (2) Exposure-Focused, Family-Based CBT for Youth with ASD and Comorbid Anxiety (FET) for children ages 4–5 (Storch et al., 2020). All participants receiving the *Cool Kids ASD* protocol received accompanying materials (a parent–child workbook) for treatment. *Cool Kids* treatment included activities based on psychoeducation, relaxation, realistic thinking skills, creation of fear hierarchies, exposure therapy, parenting of anxious behaviors, social skills, assertiveness, and structured problem solving, while FET focused exclusively on parent-guided treatment involving psychoeducation, hierarchy development, exposure therapy, and use of rewards to support exposure participation.

One-hour sessions were scheduled weekly with the child, therapist, and at least one parent in attendance. Participants continued working with their Step 1 therapists, and therapists worked directly with children to address anxiety concerns and work through fears directly with parent assistance. After pandemic onset (March, 2020), sessions were adapted to accommodate for telehealth delivery. Examples of ways sessions were adapted included:

- Screen-sharing of content and worksheets was regularly used. If completing materials during session, the therapist would email the completed worksheet to the parent during or immediately after the session. Alternatively, the parent could also complete their printed worksheet simultaneously at home.
- Despite having digital materials, the therapist continued to send hard copies to families.
- Families shared completed work by holding materials up to their screen or reading from their responses.
- Clear expectations were set when directing parents to complete reading/activities while the therapist worked with the child so that the parent did not instead use the time for other tasks around the house.
- Treatment was individualized based on various family and child factors. This included integrating more parent coaching if child engagement was limited. Therapists also used other strategies, similar to those used in person, to increase engagement and manage behavior during sessions (e.g., rewards/labeled praise, ignoring, clear effective instructions, first-then, breaks).
- Parents were often consulted in understanding appropriate expectations for the child during virtual sessions, and therapists collaborated with them to manage engagement and behavior. Some parents, for example, needed to be present to assist the therapist in keeping the child in front of the computer and on-task. In these situations, any parent content for the session was assigned to be completed prior to the session.

Participants in both the high intensity treatment condition and maintenance condition completed identical post-treatment assessments. All participants who completed 10 therapist-led sessions or who finished 12 weeks of treatment (N = 28) were considered to be Step 2 treatment completers.

Post-Treatment and 3-Month Follow-Up Assessments

Participants were scheduled for post-treatment assessments taking place approximately one week after the end of the

second 12-week phase of the study (Step 2 treatment or maintenance). Participants were administered measures identical to their midterm assessment with the exception of a participant satisfaction measure (CSQ-8).

Data Analysis

First, patterns of missing data were analyzed. Little's test for missingness suggested that data were not missing completely at random, $\chi^2 = 327.25$, $p = 004$. As indicated on the consort diagram, there was a high rate of dropout across the study (25 before March, 2020 [66% of participants enrolled to that point], 10 after March [26% of participants enrolled afterwards]), resulting in a high proportion of missing data at follow-up assessments. It is likely that participants who enrolled prior to the beginning of the pandemic dropped out due to the variety of stressors and changes during that time, including school closures, more strictly enforced physical distancing, and a transition of the study to a telehealth format. Accordingly, maximum likelihood approach was used to estimate missing data in longitudinal analyses. All data were evaluated for deviations from normality; Kolgomorov-Smirnov statistics suggested that all data were normally distributed using a threshold of −2 to +2 to indicate deviations from normality (Hair et al., 2010). There were no differences in attrition according to gender, χ^2 (1) = 0.16, $p = .69$; Hispanic/Latino ethnicity χ^2 (1) = 0.072, $p = .79$, χ^2 (1) = 0.16, $p = .69$, race χ^2 (5) = 4.20, $p = .52$. There was a significant difference according to age, with youth who dropped out being older, on average, t (94) = 2.25, $p = .027$, $d = .48$.

Next, descriptive information on the sample was presented. This included baseline characteristics as well as the proportion of youth who were classified as treatment responders after Step 1, indicated by a CGI-S score of 2 (mild severity) or less and a CGI-I score of 6 or 7 (much or very much improved). Proportion of treatment responders among those who stepped up to individual CBT were also presented across both intent-to-treat (ITT) and completer-only samples. Following the criteria used in the CAMS trial (Ginsburg et al., 2011), remission was defined as the absence of any anxiety or OCD diagnosis, a CGI-S score of 1 (borderline illness) or less, and a CGI-I score of 7 (very much improved).

To determine statistical change across therapy, multilevel modeling was used, with visits nested within participants. PARS scores were the primary outcomes and assessment point was a within-subjects variable. Models were repeated with both post-treatment (after Step 1 and maintenance or Step 1 and Step 2) and 3-month follow-up endpoints. Multilevel modeling has been recommended for psychotherapy research over traditional methods due to its handling of missing data using a maximum likelihood approach and estimates of trajectory rather than mean differences, a more reliable statistical approach to capture change (Tasca & Gallop, 2009). Intercepts were included in models to control for the significant differences between Step 1 responder groups at pretreatment (Tasca & Gallop, 2009). These analyses were replicated for secondary outcomes, including the child-report RCADS-Anxiety, as well as the parent-report CSDS-P, RCADS-Anxiety and SRS-2. Sample sizes of 50 with at least five repeated measures have been recommended for multilevel modeling, with particular statistical advantage of increasing sample (rather than assessment points) (Maas & Hox, 2005); with 76 enrolled participants and 4 assessments per participant, this study was considered well powered to detect changes across the duration of the trial. Data were analyzed using SPSS Version 27.

Results

Sample Description and Demographics

Participants were children ages 4–14 (M age = 10.39 years, SD 2.86 years), diagnosed with ASD and with a score of greater than 64 on the SRS-2, and with significant anxiety determined by a clinical severity rating (CSR) score of 4 or greater on the ADIS-IV-C/P/ASA, greater than 12 on the PARS, and with a primary concern of OCD or anxiety. Please see Table 1 for sample characteristics.

Aim 1: Clinically Significant Change

Eighteen participants (ITT: 24%; completers only: 28%) were classified as responders to Step 1. Of the 44 participants who were non-responders to Step 1 and moved on to Step 2, 23 were classified as responders at post-treatment (ITT: 52%; completers only: 70%).[1] Across the Steps 1 and 2, 43 were classified as responders (ITT: 55%; completers only: 80%).

Six participants (ITT: 8%; completers only: 9%) were in remission at the end of step 1, which represented 33% of the 18 who responded to Step 1. Of the 44 participants who moved on to Step 2, 4 (ITT: 9%; completers only: 12%) were in remission at post-treatment.

[1] Although 46 participants were classified as non-responders to Step 1, only 44 moved on to Step 2; one elected to step down with maintenance, and the other was misclassified as a responder. In the multilevel models, the participant who elected to step down to maintenance was grouped with the responders due to their identical treatment course, and the misclassified participant was excluded from analyses.

Table 2 Fixed and random effects of final models predicting anxiety severity across informants

	PARS		RCADS-child		RCADS-parent	
	Post-treat-ment	3-month follow-up	Post-treatment	3-month follow-up	Post-treatment	3-month follow-up
Fixed effects	*b*	*b*	*b*	*b*	*b*	*b*
Intercept	19.05***	18.66***	24.85***	24.97***	21.79***	21.63***
Step status[a]	3.81***	4.47***	12.61*	12.49*	10.07**	10.53**
Linear time	− 12.82***	− 9.13***	− 5.52	− 7.07	− 14.01**	− 12.55***
Time × time	3.98***	1.91***	.46	1.29	3.74	2.89**
Step status × time	9.49***	3.23	2.33	1.11	12.38^{++}	7.77^{+}
Step status × time × time	− 4.56***	− 1.02	− 1.56	− .53	− 5.32	-2.58^{+}
Random effects						
Residual	12.84***	17.78***	24.85**	80.66***	68.03***	75.61***
Intercept	2.40	2.38	12.61***	191.79***	101.99***	89.33***
Time	1.41	1.79*	− 5.52	6.37	12.00	–[b]
Time × time	1.22	–[b]	.46	–[b]	–[b]	–[b]

PARS Pediatric Anxiety Rating Scale, *RCADS* Reynolds Child Anxiety and Depression Scale

$^{+}p < .06$; $^{++}p = .050$ *p < .05, **p < .01, *** p < .001

[a]Step status refers to a binary variable of whether the participant proceeded to Step 2 or Maintenance following Step 1

[b]Random effect was redundant with other terms and not estimated

Aim 2: Effectiveness of Stepped-Care CBT

Next, symptom trajectories were tracked across the four treatment time points, repeating models for both post-treatment and 3-month follow-up endpoints. The final models for each are summarized in Table 2 and interested readers can contact the authors for modeling building information. Covariance matrices for the 3-month follow-up endpoint models are presented in Supplement 1.

PARS

The final post-treatment clinician-rated models indicated significant effects of time ($b = 9.49$, $p < .001$), quadratic time ($b = 3.98$, $p < .001$), as well as significant time × group ($b = 9.49$, $p < .001$) and time × time × group interactions ($b = -4.56$, $p < .001$). Meaning that at post-treatment (after Steps 1 and 2), those who stepped down (i.e., transitioned to maintenance) showed significantly more rapid trajectories of anxiety improvement and a positive quadratic effect, indicating steeper initial improvement from pretreatment to the end of Step 1 that became less steep during the maintenance phase (see Fig. 2). Across time points, PARS scores were significantly higher in the group that stepped up ($b = 3.98$, $p < .001$).

The final 3-month follow-up model showed significant main effects of time ($b = -9.13$, $p < .001$) and quadratic time ($b = 1.91$, $p < .001$), though the time × group and time × time × group interactions were not significant. A significant effect of step group remained ($b = 4.47$, $p < .001$), suggesting that those who stepped up had

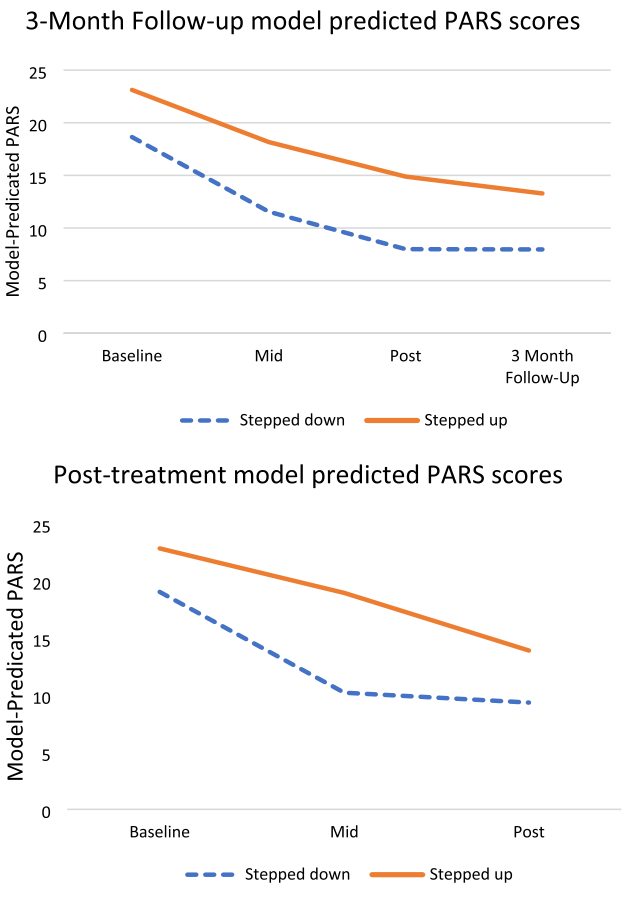

Fig. 2 *PARS* Pediatric Anxiety Rating Scale

Table 3 Fixed and random effects of final models predicting secondary outcomes: Children's Sheehan Disability Scale (functional impairment) and Social Responsiveness Scale-2 (ASD-related impairments)

	Children's Sheehan Disability Scale		Social Responsiveness Scale-2	
	Post-treatment	3-month follow-up	Post-treatment	3-month follow-up
Fixed effects	*b*	*b*	*b*	*b*
Intercept	21.11***	20.61***	92.84***	91.41***
Step status[a]	6.82*	7.33*	7.32	9.04
Linear time	− 14.53***	− 9.66***	− 34.40***	− 20.49***
Time × time	4.97**	2.19**	12.72***	4.76**
Step status × time	9.81*	4.92	26.72**	9.28
Step status × time × time	− 4.30*	− 1.51	− 12.92**	− 2.78
Random effects				
Residual	29.39***	34.49***	122.57***	145.14***
Intercept	69.40***	70.04***	345.41***	324.96***
Time	11.19*	4.79	71.13*	25.87*
Time × time	_[b]	_[b]	_[b]	_[b]

[+]p = .069 *p < .05, **p < .01, *** p < .001

[a]Step status refers to a binary variable of whether the participant proceeded to Step 2 or Maintenance following Step 1

[b]Random effect was redundant with other terms and not estimated

significantly more severe anxiety across the duration of the trial. Integrating findings from the two models with post-treatment and 3-month follow-up endpoints, this suggests that although the acute effects of treatment were more robust for those who responded to Step 1, by three-month follow-up, there were no longer significant differences across groups in symptom trajectories over the long-term follow-up.

R-CADS-Anxiety (Parent-Report)

In the final post-treatment model, significant effects of time ($b = -14.01$, $p = .008$) and step group ($b = 10.07$, $p = .006$) were found, suggesting that symptoms decreased over treatment in a linear fashion and symptoms were more severe in the group who stepped up. The step group × time interaction was trending ($b = 12.38$, $p = .050$), suggesting symptoms reduced more quickly in the group that stepped down at a trend level.

Three-month follow-up results found a similar pattern; significant time ($b = -12.55$, $p < .001$) and step group ($b = 10.53$, $p = .003$) effects were found, as well as a positive quadratic effect of time ($b = 2.89$, $p = .008$). Both the step × time and step × time × time interactions were trending towards significant (step × time: $b = 7.77$, $p = .055$; step × time × time: $b = -2.58$, $p = .056$), indicating that symptoms reduced more quickly and in a more positive quadratic manner at a trend level across the longer-term follow-up. See Table 2 for a summary of final model coefficients.

R-CADS-Anxiety (Child-Report)

In the final post-treatment and three-month follow-up models, those who stepped up reported significantly higher anxiety across assessment points (post: $b = 12.61$, $p = .024$; three-month: $b = 12.49$, $p = .020$). Significant time, quadratic time, or group × time effects were not found in the final model predicting child-reported anxiety, though a significant main effect of time was found in prior models that did not include interaction terms (post: $b = -5.10$, $p < .001$; 3-month: $b = -6.28$, $p = .011$). See Table 2.

CSDS-P In the final post-treatment model, CSDS-P scores were significantly associated with step group ($b = 6.83$, $p = .014$), time ($b = -14.53$, $p < .001$), quadratic time ($b = 4.97$, $p = .003$), the time × step group interaction ($b = 9.81$, $p = .019$), and the quadratic time × step group interaction ($b = -4.30$, $p = .034$), echoing PARS results.

The time × step group interaction and quadratic time × step group interactions were no longer significant in the 3-month follow-up model, though the fixed effect of step group ($b = 7.33$, $p < .010$), time ($b = -9.66$, $p < .001$), and quadratic time ($b = 2.19$, $p = .004$) remained significant, again repeating the pattern of results in PARS analyses. See Table 3 for final model coefficients.

SRS-2 The final post-treatment clinician-rated models indicated a significant time × group interaction ($b = -26.72$, $p = .003$) and time × time × group interactions ($b = -12.92$, $p = .003$), as well as significant main effects of time ($b = -34.40$, $p < .001$) and quadratic time ($b = 12.72$,

Table 4 Comparison of Step 1 Responders and Non-Responders at Baseline

	Step 1 Responders $n=18$	Step 1 Non-Responders $n=46$	t	Effect size [95% CI][b]
Anxiety severity				
PARS, M (SD)	19.2 (3.4)	22.7 (3.8)	3.37**	.94 [.36, 1.50]
RCADS-anxiety (child), M (SD)	24.8 (21.1)	38.1 (18.0)	2.18*	.70 [.052, 1.35]
RCADS-anxiety (parent), M (SD)	21.2 (8.4)	31.8 (17.3)	3.29**	.70 [.13, 1.26]
Emotional and behavioral symptoms				
CBCL-internalizing	11.9 (5.9)	17.7 (10.3)	2.81**	.62 [.064, 1.18]
CBCL-externalizing	13.0 (8.8)	14.6 (9.3)	0.66	.18 [−.37, .72]
Parental emotional symptoms				
DASS-depression	1.4 (2.4)	2.3 (2.7)	1.19	.33 [−.22, .88]
DASS-anxiety	1.5 (2.5)	1.9 (2.4)	0.58	.16 [−.38, .71]
DASS-stress	4.6 (3.5)	5.3 (3.7)	0.69	.19 [−.36, .74]
ASD symptoms				
SRS-2, M (SD)	90.2 (19.4)	99.9 (25.8)	1.45	.40 [−.15, .95]
Impairment				
CSDS-child, M (SD)	9.9 (7.8)	16.6 (8.5)	2.47*	.79 [.14, 1.45]
CSDS-parent, M (SD)	21.4 (8.2)	27.4 (10.6)	2.17*	.60 [.046, 1.16]

CBCL Child Behavior Checklist, *PARS* Pediatric Anxiety Rating Scale, *RCADS* Reynolds Child Anxiety and Depression Scale, *CSDS-Child* Child Sheehan Disability Scale—Child, *CSRS-Parent* Child Sheehan Disability Scale—Parent, *DASS* Depression, Anxiety, and Stress Scale

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

$p < .001$). Step group was not significantly associated with greater SRS-2 symptoms in the final model, though in prior models that did not include interaction terms, those who stepped up reported significantly higher symptoms across the course of the trial ($b = 12.03$, $p = .034$).

The final three-month follow-up model showed significant main effects of time ($b = -20.49$, $p < .001$) and quadratic time ($b = 4.76$, $p = .001$). In the prior models that did not include interaction terms, there was also a significant effect of treatment group on symptoms ($b = 12.39$, $p = .027$), such that those who stepped down had less severe ASD-related impairments across timepoints. See Table 3 for a summary of the final model and interested readers can contact the authors for modeling building information.

Aim 3: Predictors of Response to Step One Parent-Led Bibliotherapy

As summarized in Table 4, participants who were responders after Step 1 (parent-led bibliotherapy) had significantly less severe anxiety at pre-treatment across child, parent, and clinician informants (PARS, RCADS-Anxiety), significantly more severe internalizing symptoms (CBCL), as well as significantly less pre-treatment functional impairment across parent and child informants (CSDS). There were no significant differences in parent-reported ASD-related impairments (SRS-2), parent-reported externalizing symptoms (CBCL), or parent self-reported depressive, anxiety, or stress symptoms (DASS-21).

Satisfaction

The mean total treatment satisfaction score on the CSQ-8 was 28.8, indicating a mean response to each item of 3.6, falling between 3 ("good") and 4 ("excellent"), suggestive of high satisfaction with the program overall. There were no significant differences between treatment groups, $t(45) = 0.86$, $p = .39$, $d = 0.26$.

Discussion

We examined a stepped-care treatment model for autistic children with co-occurring anxiety. Partially consistent with our hypothesis, 28% percent of children responded to Step One. This is modestly less than past studies in children with anxiety or PTSD (Rapee et al., 2017; Salloum et al., 2022a, 2022b). It may be that the complexity of ASD-anxiety co-occurrence is associated with more attenuated response rates to PLTA-CBT. Indeed, while response rates for CBT for anxiety in autistic youth are comparable to those of typically developing youth with anxiety (Storch et al., 2013, 2015; Wood et al., 2015, 2020), the magnitude of response is often less in the former group.

Consistent with our hypothesis, 80% of families who completed the full program were classified as responders. Seventy percent of completers who received Steps 1 and 2 were classified as treatment responders. Caregivers were generally very satisfied with the treatment approach, and satisfaction did not differ as a function of those that received Steps 1 and 2, versus Step 1 before entering maintenance. That said, a large portion of families (40%) dropped out of treatment, particularly during the period before and around the beginning of COVID-19 when treatment was in-person and then transitioned to virtual. Considering ITT analyses, response rates were substantially lower (52% who received Steps 1 and 2, 55% overall). While rates of attrition were similar to other studies of stepped-care (), and influenced by the onset of the COVID-19 pandemic, these findings suggest that stepped treatment may be associated with higher rates of attrition relative to those seen in more traditional CBT models for anxiety in autistic youth (Wood et al., 2020). It may be that parents did not feel adequately supported in Step One, that the extended two-step treatment process was longer than a typical course of treatment and thus left more opportunity for dropout, or that certain variables are associated with attrition (i.e., traveling to treatment appointments before the study transitioned to telehealth). Reduced attrition after moving to virtual may reflect the acceptability of this approach.

Analyses of the primary outcome measure, the clinician-rated PARS, suggested that autistic youth who transitioned to the maintenance phase experienced more rapid symptom reduction, particularly from pre-treatment to the end of Step 1 (as would be expected based on the design of the trial), though this better rate of improvement maintained from Step 1 to Step 2, as well. By three-month follow-up, however, there were not significant differences in rates of symptom improvement (though symptoms were more severe across timepoints in the group who stepped up to individual CBT). This pattern of findings was also replicated for improvements in parent-reported functional impairment and ASD symptoms.

Regarding predictors of Step 1 outcomes and consistent with our hypothesis, autistic youth with more severe anxiety and impairment required more extensive individual therapy in addition to the brief parent-led approach to achieve sufficient gains. More severe symptoms among the group that stepped up were found in both baseline analyses (anxiety severity across informants; functional impairment across informants) as well as longitudinal analyses (anxiety severity across informants; parent-report ASD-related impairments). While modest, this finding suggests that a meaningful portion of children—particularly those with less severe anxiety—could receive a focused parent-led intervention with minimal therapist support and experience significant gains. Youth who responded to this intensity of treatment tended to maintain gains at post-treatment and 3-month follow-up. In individual CBT, youth with more severe anxiety tend to experience more rapid improvement (Kennedy et al., 2021; Pettit et al., 2016; Skriner et al., 2019); in contrast, this study suggests parent-guided treatment benefits those with less severe symptoms most, and thus may be an especially appropriate treatment option for youth less impacted by anxiety, as one might expect. Neither parental depressive symptoms nor child externalizing symptoms predicted Step 1 outcome, which is inconsistent with other findings in PTSD (), as well as in autistic children who received a full course of therapy (Storch et al., 2021). Rates of parental depression were relatively low suggesting a floor effect. Exclusion criteria limited involvement of significantly disruptive youth which may have affected findings. Alternatively, the Step 1 treatment approach was sufficiently flexible to advise on managing modest disruptive behavior.

There are several limitations when interpreting these results. First, attrition was high in this project but similar to other stepped-care intervention studies (Salloum et al., 2022a, 2022b). Second, methodology was forced to shift as a function of the COVID-19 pandemic, and individual/family stressors increased during this time with homeschooling and other psychosocial stressors. Third, therapy sessions were initially provided in person and then moved to Zoom after the onset of the pandemic. While this reduced some treatment barriers, many youth in Step 2 struggled with the video platform of treatment requiring adaptations. On balance, the telehealth modality was well suited for in-session exposure practice in their home environment, and maximized session time as parents did not get stuck in traffic, become delayed by parking issues, etc. Fourth, autistic girls were underrepresented in our sample. Fifth, people with intellectual disability were not included in this study given the verbal nature of CBT; results may not generalize to autistic youth with intellectual disability. Sixth, although our sample composition was approximately one third Hispanic ancestry (reflecting the Houston metropolitan), other race/ethnic groups did not reflect the Houston metropolitan. Thus, findings may not generalize to these groups and more diverse samples are needed in future studies. Finally, this trial was underpowered to perform non-inferiority analyses. Within those limitations, however, this assessment indicates that a meaningful number of autistic children and anxiety can be helped through a parent-led therapist assisted protocol. Of those that required additional intervention, 10 family-based CBT sessions were associated with treatment gains, with 80% of families who completed treatment being considered responders. Those that responded to Step One were typically less anxious than non-responders, but able to maintain their gains over the course of the maintenance and short-term follow-up phases.

In sum, our findings indicate that a modest percentage of autistic youth with anxiety (28%) respond to a low-intensity parent-led CBT intervention, and that baseline anxiety and impairment inversely predicted outcome. Among those who completed treatment, 80% were responded although attrition was high overall during the study. Understanding tailoring variables and predictors of treatment outcomes is critical for next steps to understand for whom a stepped-care model may be most appropriate, as well as how best to retain participants in future research. This report suggests autistic youth with less severe anxiety may be more appropriately directed to a brief parent-led program, but those with more severe anxiety require a full treatment course. Future adequately-powered studies should consider testing the non-inferiority and cost-effectiveness of a stepped-care approach compared to a typically-delivered CBT intervention.

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Declarations

Conflict of interest Dr. Eric Storch receives grant support from NIH, the Ream Foundation, Greater Houston Community Foundation, International OCD Foundation, and Texas Higher Education Coordinating Board. He receives book royalties from Elsevier, Springer, American Psychological Association, Jessica Kingsley, Oxford, and Lawrence Erlbaum. He holds stock in NView, where he serves on the clinical advisory board. He was a consultant for Levo Therapeutics, and is currently a consultant for Biohaven Pharmaceuticals and Brainsway. He co-founded and receives payment from Rethinking Behavioral Health, which is a consulting firm that provides support for implementing evidence-based psychological treatment strategies. Dr. Guzick receives grant support from the REAM Foundation and the Texas Higher Education Coordinating Board. Dr. Goodman has received research support from Brainsway, Biohaven Pharmaceutics and the NIH; Medtronic donated devices to a research project; and he received consulting fees from Biohaven and Neurocrine Biosciences. Dr. Alison Salloum receives grant support from The Norwegian Centre for Violence and Traumatic Stress Studies, Department of Education, Office of Special Education and Rehabilitative Services and royalties from Taylor and Francis. Further, Dr. Salloum is a co-author of Stepping Together a treatment manual used in stepped care TF-CBT and holds a licensing agreement with Guilford Press for adaptation of some of the handouts and worksheets in the manual. Dr. Salloum is also a national trainer for TF-CBT. Drs. Schneider, Berry, Goin-Kochel, Candelari, Voight, and Quast report no conflicts of interest. Mr. Olsen, Ms. Ramirez, Ms. McNeel, Ms. Weinzimmer, and Ms. Cepeda report no conflicts of interest.

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