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ORIGINAL ARTICLE

Effects of Cognitive-Behavioral Therapy on Anxiety in Children with Autism Spectrum Disorders: A Randomized Controlled Trial

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Abstract We compared the effects of a 16-week Cognitive-Behavioral Therapy (CBT) program and a Social Recreational (SR) program on anxiety in children with Autism Spectrum Disorders (ASD). Seventy children (9–16 years old) were randomly assigned to either of the programs ($n_{CBT} = 36$; $n_{SR} = 34$). Measures on child's anxiety using the Spence Child Anxiety Scale—Child (SCAS-C) and the Clinical Global Impression—Severity scale (CGI-S) were administered at pre-, post-treatment, and follow-ups (3- and 6-month). Children in both programs showed significantly lower levels of generalized anxiety and total anxiety symptoms at 6-month follow-up on SCAS-C. Clinician ratings on the CGI-S demonstrated an increase in the percentage of participants rated as "Normal" and "Borderline" for both programs. Findings from the present study suggest factors such as regular sessions in a structured setting, consistent therapists, social exposure and the use of autism-friendly strategies are important components of an effective framework in the management of anxiety in children and adolescents with ASD.

Keywords Autism spectrum disorder · Anxiety · Cognitive-behavior therapy · High-functioning autism · Asperger syndrome · Social recreational

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Introduction

Autism spectrum disorders (ASD) as defined by the *DSM IV*, is characterized by qualitative impairments in social interaction and communication, and restricted, repetitive and stereotyped patterns of behavior, interests and activities [1]. ASD includes diagnoses of Autistic Disorder, Pervasive Developmental Disorders Not Otherwise Specified (PDD-NOS) and Asperger Syndrome (AS), and encompasses children with a wide range of abilities. Anxiety-related concerns are among the most common presenting problems for school-going children and adolescents with ASD [2]. Levels of anxiety in children with Asperger Syndrome have been found to be similar to those in children diagnosed with social phobia and greater than those in typically-developing children [3]. A systematic review of studies on the prevalence of anxiety in children and adolescents with ASD suggested that between 11 and 84% of them experience some degree of impairing anxiety [4]. Stereotypical behaviors, such as echolalia, twirling, rocking, flicking, hand flapping and repetitive questioning, often increase when children are distressed or anxious [5, 6]. High anxiety subscores were found for separation anxiety, social anxiety and obsessive-compulsive disorder in children with ASD [7].

Psycho-social treatments, such as Cognitive-Behavioral Therapy (CBT), have been documented to be effective in treating anxiety symptoms among non-ASD children and their families [8–10]. CBT helps the individual identify and correct cognitive deficiencies and distortions associated with anxiety so as to effect constructive changes in their behaviors and emotions. Through CBT, individuals can learn skills to modify their thoughts and beliefs, as well as problem-solving strategies to improve their interaction with others in effective and appropriate ways, thereby promoting self-regulation [11].

Children who are clinically anxious have been reported to have an information-processing bias, whereby they selectively attend to threat-related information, resulting in misinterpretation of ambiguous situations to be threatening [12]. Similarly, children with ASD have weak central coherence, i.e., impairments in the integration of information into a meaningful whole, leading to flawed perceptions of the situation. Their difficulties are exacerbated by social information processing problems (e.g., misinterpretation of ambiguity in social context and situations), which in turn gives rise to anxiety [13]. As such, there has been recent interest in the use of CBT in the management of anxiety in children with ASD and Asperger Syndrome. Studies have suggested that CBT may help lessen anxiety symptoms in children with ASD [14–17]. Findings from these studies suggest that CBT can reduce the level of anxiety in children with ASD, when compared to wait-list controls. Parent involvement was also found to be a helpful component [16]. Whilst findings have been encouraging, control groups used in these studies were wait-list controls, hence giving rise to the possibility that reported improvements could have been attributed to contact time with the therapist and session structure rather than the program content alone.

Other intervention programs that include social recreational activities may also be beneficial for children with ASD. Participation in social recreational activities may provide increased opportunities for social interaction, friendship development, and social skills building in children with ASD. These in turn, may boost their self-confidence, enhance self-worth and reduce anxiety and thus facilitate long-term mental and physical health [18–22].

Because of the high prevalence of anxiety in ASD, finding effective evidence-based treatments to address anxiety in this population is important [4]. There are currently no studies that compared CBT to other forms of non-CBT based treatments such as social

recreational activities. In the present randomized controlled trial, we aimed to address this limitation in the literature by comparing the effects of a 16-week CBT program focusing on anxiety in children with ASD with a 16-week Social Recreational (SR) program. In view of the current literature, we hypothesized improvements in child-reported measure of anxiety for both the CBT and SR groups, but that the CBT group would demonstrate superiority over the SR group, with participants in the CBT group showing greater improvements on the anxiety measures.

Method

Participants

A total of 70 children diagnosed with ASD and anxiety-related issues, aged 9–16 years (66 boys and 4 girls) participated in the study. They were randomly assigned to the CBT program ($n_{CBT} = 36$) or SR program ($n_{SR} = 34$). These participants were recruited through invitation letters to parents of children diagnosed with ASD attending the Child Guidance Clinic (CGC, an outpatient mental health clinic for children and adolescent), advertisements placed at the CGC, and referrals from attending clinicians at CGC and other agencies such as paediatricians and schools. Out of 70 children who were randomized into one of the two groups, six participants did not complete the 16-week program. Reasons for drop-out included lack of interest, clashes with school schedules, preferred enrolment in other services, and changes in dosage of medication due to other co-morbid psychiatric conditions. Figure 1 illustrates the CONSORT flow diagram and the CONSORT Statement 2001 Checklist can be found in the "Appendix".

These children were included in the study if they fulfilled the following inclusion criteria: (a) 9–16 years old; (b) clinical diagnosis of Autism, Asperger syndrome, PDD(NOS) or ASD by the DSM-IV criteria [1]; (c) had a classification of "Autism" or "Autism Spectrum" on the Autism Diagnostic Observation Schedule (ADOS) [23]; (d) Verbal Comprehension of 80 and above and Perceptual Reasoning skills of 90 and above as assessed on the Wechsler Intelligence Scale for Children—Fourth Edition [24]; and (e) for children on medication, no change of medication dosage 1 month prior to the start of the study and throughout the duration of the study was required. The criteria for Verbal Comprehension and Perceptual Reasoning was set according to the nature of a CBT program, for example, the child needs to be able to express his thoughts or cognitions in some forms such as verbal expression or writing down his/her ideas. In addition, the child needs to demonstrate the ability to understand the theory or strategies taught by the therapists in order to fully benefit from the CBT program. Table 1 presents demographics of the participants.

Measures

Child Anxiety

Child's anxiety was assessed using the Spence Child Anxiety Scale—Child (SCAS-C) [25]. The SCAS-C was developed to assess the symptoms of anxiety broadly in line with the dimensions of anxiety as proposed by the DSM-IV. The SCAS-C assesses six domains of anxiety including generalized anxiety, panic/agoraphobia, social phobia, separation anxiety, obsessive compulsive disorder, and physical injury fears. A total anxiety score can be obtained by summing up the six domains. This measure consists of 44 items; of which

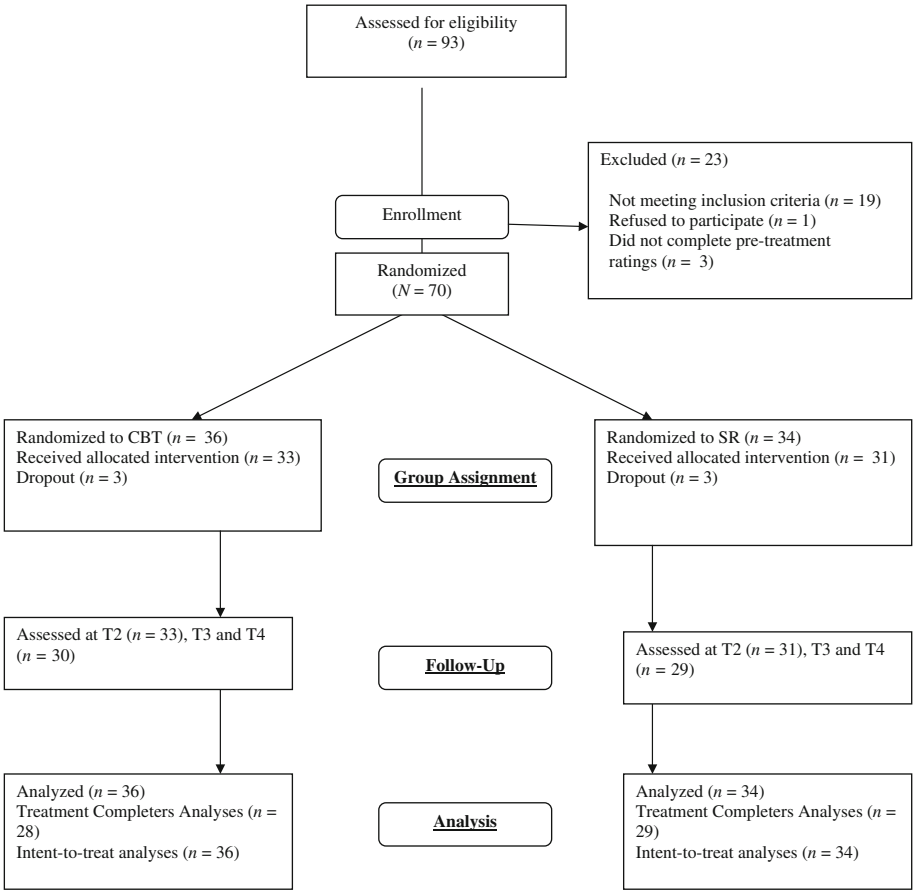

Fig. 1 CONSORT flow diagram. *CBT* cognitive-behavioral therapy, *SR* social recreational, *T1* pre-treatment, *T2* post-treatment, *T3* 3-month follow-up, *T4* 6-month follow-up

38 reflect specific symptoms of anxiety and six relate to positive, filler items to reduce negative response bias. Participants were asked to rate themselves on the items based on the descriptions given on a four-point Likert scale (never, sometimes, often or always). To facilitate understanding of and accuracy of rating, participants were taught the concept of frequency terms: 'never, sometimes, often or always', with an interactive computer application that illustrates the frequency of occurrence of neutral items (e.g., fruits). The items were also enhanced with visual representation using pie-chart proportions. Subsequently, neutral items were given to participants as practice items to check understanding of the concept of frequency.

In a large sample of children from a community setting, the internal consistency of the SCAS-C (sub-scales and total score) ranged from adequate to high: (1) .82 for panic attack, (2) .74 for separation anxiety, (3) .60 for physical injury fears, (4) .74 for social phobia, (5) .76 for obsessive compulsive, and (6) .77 for generalized anxiety [25]. In the present sample, the internal consistency for the SCAS-C pre-treatment scores were: (1) .73 for panic attack, (2) .62 for separation anxiety, (3) .46 for physical injury fears, (4) .68 for

Table 1 Demographics of participants (based on intent-to-treat)

	CBT ($n = 36$)	SR ($n = 34$)
Mean age (SD)	11.33 (2.03)	11.09 (1.53)
Gender		
Male	34	32
Female	2	2
Ethnicity		
Chinese	35	30
Malay	1	2
Indian	0	1
Others	0	1
Diagnostic group		
Autism/PDD-NOS	30	28
Asperger syndrome	6	6
Cognitive functioning		
Verbal comprehension	100.25 (13.97)*	93.06 (12.81)
Perceptual reasoning	108.00 (12.26)	105.94 (11.07)
Medication status		
On medication	6	5
Not on medication	29	28
Unknown	1	1

CBT cognitive behavior therapy, *SR* social recreational, *T1* pre-treatment, *T2* post-treatment, *T3* 3-month follow-up, *T4* 6-month follow-up

* Significantly different from SR group, $p < .01$

social phobia, (5) .58 for obsessive compulsive disorder, (6) .69 for generalized anxiety, and (7) .88 for total SCAS-C.

Severity of Anxiety

The severity of the participants' anxiety was assessed using the Clinical Global Impression—Severity (CGI-S) [26]. Clinicians were asked to rate their observations on the severity of the participants' anxiety on a 7-point scale from normal to extremely ill respectively. The CGI-S has been useful in several clinical trials involving children with ASD [27].

Procedures

The Institute of Mental Health's Clinical Research Committee (CRC Ref: 130/2005) and the National Healthcare Group's Domain Specific Review Board (DSRB Ref: A/05/091) (Singapore) approved this present study. Participation in the study was voluntary and written parental consent was obtained for all children participating in the study. In addition, children above 12 years old provided consent while those below 12 years old provided assent to participation. All personal identifiers were removed and responses obtained were kept confidential.

Subsequently, all participants were screened to ascertain that they fulfilled the study inclusion criteria (see section on "Participants"). Those who met the inclusion criteria were stratified based on their age (9–12 years old or 13–16 years old) and randomly assigned to either the CBT group or the SR group to form groups of 3–4 children. This was done manually by a research assistant using simple block randomization with the following treatment assignment within each block: ABBAABBA (A = CBT and B = SR). Clinicians were blinded to the group assignment. Parents were not actively informed about group assignment till the end of the study. Participants allocated to SR group were given the option of attending CBT group upon participation completion in the study. Child and clinician measures were taken at pre-treatment (T1), post-treatment (T2, immediately upon completion of the 16-week program), at 3-month follow-up (T3) and at 6-month follow-up (T4). Because English is the official instructional language in Singapore schools, the CBT and SR programs were conducted in English.

CBT Program

The CBT program was developed by Psychologists from the Child Guidance Clinic and the Autism Resource Centre (Singapore). Modifications and adaptations were made from various CBT programs such as The Coping Cat Program [28], Exploring Feelings [29] and unpublished anxiety management programs from the CGC and Autism Resource Centre. For example, we incorporated strategies found to be effective with children with ASD such as the use of structure, visual strategies, role-plays, and Social Stories [30]. The CBT program was also tailored to meet the cultural and developmental profiles of children with ASD in the Asian population. The scenario examples and worksheets were also set in context that was more meaningful to the children in Asia. We also modified the metaphorical use of Toolbox from the Exploring Feelings program [29] to the Cleaning Toolbox.

The manualized CBT program consisted of sixteen 90-min weekly sessions delivered in small groups of 3–4 participants. Each group was conducted by 2 therapists who were trained to conduct the program. The CBT program comprised three main sections. Part one (sessions 1–3) focused on the recognition and understanding of emotions, both in the participant himself and in others. Participants were taught to recognize different types of emotions (e.g., happy, sad and angry) with an emphasis on anxiety. Differences in situational triggers, facial expressions, behaviors and gestures, speech, physiological reactions, and thoughts associated with the various emotions were highlighted. Participants also identified their own anxiety triggers and rated these in terms of intensity. Part two (sessions 4–9) focused on anxiety management techniques. Participants were taught the techniques in hierarchical levels of difficulty, such as through 'ventilation' in the form of physical activities, relaxation skills (breathing exercises and muscle relaxation techniques), enlisting assistance from others (social aspect involved) and cognitive reconstruction (through identification and replacement of cognitive errors with positive and helpful ways of thinking). These strategies and skills were presented to the participants with the use of visual representation in the form of 'cleaning tools' to facilitate recall.

Participants practiced with the therapists and were given homework assignments and cue cards to encourage generalization and practice outside of the therapy setting. Part three (sessions 10–16) focused on problem-solving strategies based on the STAR strategy, which has been used at the Child Psychiatric Service at the University of Iowa Hospitals and Clinic since 1980 [31]. STAR is an acronym for *S*TOP (identify that one is anxious and needs to calm down), *T*HINK (think of possible ways to calm down and/or solutions to the

problem), *A*CT (execute a chosen plan) and *R*EFLECT (evaluate the outcome of the selected plan and make adjustment as appropriate). Participants practiced utilizing the problem solving strategy on different levels, i.e., in theory, in imagination, in role-play and in-vivo (when possible). This was repeated for the various different situational triggers of anxiety identified by participants in the first part of the program.

Importantly, although the program was manualized, the instructional method retained flexibility and allows for differences in therapy facilitation between the younger group (9–12 years old) and the older group (13–16 years old). Therapists need to be sensitive to the developmental differences between children of different ages and intellectual maturity for therapy to be effective. While games and activities were incorporated to enhance learning, their complexity and goals varied according to the learning pace of the participants. For the younger group, the concepts were explained or illustrated in simpler terms. The older children were better able to, and thus encouraged to rationalize their thoughts or problems. Coping strategies were also discussed and taught at age-appropriate levels, for example, a 9-year old could have been encouraged to approach a teacher when teased by his classmate, whereas a 15 year-old with a similar problem could have been encouraged to deal with the teasing with a 'clever' retort or seek solace from a peer. Problem-solving practices were dependent on individual issues and contexts which allowed flexibility and adaptation of the program sensitive to the needs of each child.

SR Program

The SR group received a 16-week manualized SR program developed by Psychologists and Research Assistants at CGC. Similarly, it also consisted of sixteen 90-min weekly session delivered in small groups of 3–4 participants. Each group was run by 2 therapists who were trained to conduct the program. Similar to the CBT program, common strategies found to be effective with children with ASD were also incorporated, such as the use of structure and visual cues to encourage behavioral regulation expected in a group setting. The range of activities in the SR program was designed for exposure to age-appropriate activities that would have been of interest to neuro-typical children of a similar age group. These activities were categorized into individual or group activities. Individual activities aimed at fostering self-development skills, such as teaching the child to prepare a simple meal, and self-engagement behaviors such as doing crafts (e.g., paper cutting, folding or using clay). Other activities were intellectually simulating (e.g., word puzzles) or were aimed at improving motor coordination skills (e.g., magic tricks). Group activities provided the participants with opportunities to learn and practice pro-social skills through cooperative games such as board games and treasure hunts. In their interaction with others, the participants were reminded of social etiquette such as taking turns and playing fair. Homework tasks given included related activities the participants could try outside of therapy sessions.

Participants in the SR group did not receive any specific instruction (which represented the main components of the CBT program) on emotional regulation and problem solving techniques (STAR), repeated practice, and exposure tasks. They may have been taught social skills depending on available opportunity, for example, the therapist addressing the child's inappropriate requests when the situation arose. However, this was done primarily to model the group sessions after the structure of local academic classroom settings.

Treatment Integrity

The integrity of CBT program and the SR program were assessed in the following ways. First, both programs were manualized to increase adherence to intervention procedures. Second, the sessions were videotaped and viewed by an independent rater who completed checklists that described the specific themes to be covered for each session. Results showed that adherence to both of the programs were above 95%.

Data Analysis

Sample size was determined based on the following method. Based on a study conducted by Spence [25], the mean total anxiety score in a clinical sample was around 30 (SD = 18) on the SCAS-C [25]. We had expected to demonstrate a 50% reduction in the level of anxiety from a score of 30–15 for the experimental group with the assumption that no reduction in the level of anxiety in the control group would be observed. In order to achieve a 50% clinical reduction with a power of 90% and a 2-sided test of 5%, a minimum of 31 subjects for each group would be required for a significant statistical result.

Descriptive statistics were used to analyze the demographic characteristics of participants such as age, gender, ethnicity, and diagnosis groups. A series of repeated measures analysis of variance were used. Separate analyses were conducted for treatment completers and for intent-to-treat condition. The intent-to-treat analysis was conducted with participants' last available scores carried forward to post-treatment and 3-month follow-up. The intent-to-treat analysis was limited to 3-month follow-up based on Kenardy's et al. recommendation [32].

The number of participants who improved, deteriorated or did not change was calculated by the Reliable Change Index (RCI) as described by Jacobson and Truax ($RC = (T_x - T_1)/Sdiff$, where T_1 is the participant's pre-treatment score, T_x is the post-treatment/follow-up score, and Sdiff is the standard error of the difference between the two test scores) [33]. Using the RCI, participants were classified as improved ($RCI \geq 1.96$), no change ($-1.96 > RCI < 1.96$), or deteriorated ($RCI \leq -1.96$) based on total anxiety scores, where lower scores at post-treatment/follow-up indicated improvement.

Results

Recruitment of participants started in February 2007 and ended in August 2008; post-treatment (including 3- and 6-month follow-up) assessments were completed by June 2009. Pre-treatment group differences for treatment completers were assessed with chi-square tests and t-tests. The groups did not differ significantly on the demographics as presented in Table 1 with one exception—those in the CBT group had higher verbal comprehension skills. Means and standard deviations of SCAS-C at all four time points for the two groups are presented in Tables 1 and 2 respectively. Notably, the pre-treatment total anxiety scores for both groups were higher than the normative data for SCAS-C [25].

Treatment Completers Analyses

A series of repeated measures analysis of variance were conducted to compare child reports of anxiety across time (T1 pre-treatment, T2 post-treatment, T3 3-month follow-up, and T4 6-month follow-up) and between groups (CBT vs. SR).

Table 2 Means and standard deviations for child reports of anxiety

Measures	SCAS-C			
	T1	T2	T3	T4
Panic attack				
CBT	4.00 (3.42)	3.50 (5.18)	2.61 (3.55)	2.54 (3.53)
SR	4.34 (3.90)	3.03 (3.20)	3.21 (5.17)	1.97* (2.11)
Separation anxiety				
CBT	4.39 (2.99)	3.29 (2.88)	2.93 (2.78)	3.21 (3.05)
SR	5.28 (3.45)	3.93 (2.89)	4.21 (4.30)	3.10 (3.28)
Physical injury				
CBT	3.50 (2.43)	3.46 (2.27)	3.54 (2.53)	3.11 (2.51)
SR	5.03 (2.65)	3.97 (2.84)	4.21 (2.94)	3.28 (2.51)
Social phobia				
CBT	5.71 (3.71)	5.04 (3.32)	4.79 (3.81)	4.68 (3.51)
SR	6.31 (3.97)	4.66 (2.77)	5.55 (4.14)	4.55 (3.34)
Obsessive compulsive				
CBT	6.39 (3.73)	6.43 (4.12)	6.25 (3.79)	4.79 (3.65)
SR	8.24 (3.38)	7.59 (4.51)	6.59 (4.40)	5.34 (3.64)
Generalized anxiety				
CBT	5.96 (3.55)	4.82 (3.21)	4.36 (3.31)	3.21* (1.95)
SR	5.83 (3.10)	4.45 (2.52)	4.66 (3.86)	2.93*$^{+}$ (2.07)
Total score				
CBT	29.96 (14.91)	26.54 (15.57)	24.26 (15.24)	21.54* (14.82)
SR	35.03 (14.13)	27.62* (13.57)	28.41 (20.60)	21.17*$^{+}$ (11.97)

CBT cognitive-behavioral therapy, *SCAS-C* spence child anxiety scale—child, *SR* social recreational, *T1* pre-treatment, *T2* post-treatment, *T3* 3-month follow-up, *T4* 6-month follow-up

Means are based on data for treatment completers: CBT, $n = 28$; SR, $n = 29$

* Significantly different from T1, $p < .01$, *$^{+}$ Significantly different from T2, $p < .01$

Child Reports on Anxiety

Analyses from the repeated measures showed that there were significant main effects for Time for panic attack, $F(3, 134) = 6.10$, $p = .001$, $\eta^2 = .11$, generalized anxiety, $F(3, 129) = 3.28$, $p = .03$, $\eta^2 = .06$, and total anxiety score, $F(3, 124) = 3.03$, $p = .04$, $\eta^2 = .06$. Post-hoc comparisons of the main effects showed that both groups reported significantly fewer generalized anxiety and total anxiety symptoms at T4. In addition, children in the SR group also reported significantly fewer total anxiety symptoms at T2 and significantly fewer panic attack symptoms at T4. However, no significant main effect for Group and interaction effects for Time $\times$ Group was found, indicating that both groups did not differ across time.

Reliable Change Index

The proportion of participants showing deterioration, no change, and improvements are presented in Table 3. At T2, the proportion of participants who improved based on child

Table 3 Proportion of participants showing deterioration, no change, and improvements for SCAS-C

Measures	T1–T2		T1–T3		T1–T4	
SCAS-C	CBT ($n = 32$)	SR ($n = 31$)	CBT ($n = 30$)	SR ($n = 29$)	CBT ($n = 29$)	SR ($n = 29$)
Deteriorated	3 (9.38%)	1 (3.23%)	2 (6.67%)	2 (6.90%)	3 (10.34%)	0 (0%)
No change	23 (71.88%)	25 (80.65%)	19 (63.33%)	17 (58.62%)	13 (44.83%)	13 (44.83%)
Improved	6 (18.75%)	5 (16.13%)	9 (30%)	10 (34.48%)	13 (44.83%)	16 (55.17%)

CBT cognitive behavior therapy, *SCAS-C* spence child anxiety scale—child, *SR* social recreational, *T1* pre-treatment, *T2* post-treatment, *T3* 3-month follow-up, *T4* 6-month follow-up

Table 4 Severity of anxiety based on CGI-S

	CBT				SR			
	T1 (%)	T2 (%)	T3 (%)	T4 (%)	T1 (%)	T2 (%)	T3 (%)	T4 (%)
Normal	6.06	21.21	18.52	28.57	0	6.45	26.92	37.04
Borderline	18.18	36.36	33.33	32.14	12.90	25.81	30.77	25.93
Mildly ill	54.55	30.30	33.33	32.14	48.39	54.84	23.08	33.33
Moderately ill	21.21	12.12	14.81	7.14	29.03	12.90	19.23	3.70
Markedly ill	0	0	0	0	9.68	0	0	0

CBT cognitive-behavioral therapy, *CGI-S* clinical global impression—severity, *SR* social recreational, *T1* pre-treatment, *T2* post-treatment, *T3* 3-month follow-up, *T4* 6-month follow-up

reports of anxiety was 18.75% for the CBT group and 16.13% in the SR group. The proportion of participants who improved in the CBT group at T3 and T4 increased to 30 and 44.83% respectively. On the other hand, 34.48 and 55.17% of participants in the SR group improved at T3 and T4. Chi-squares analyses did not reveal any significant differences between the two groups.

Severity of Anxiety

The percentages of participants showing improvements on the CGI-S are presented in Table 4. In both groups, the percentage of participants in the "Normal" range increased from T1 to T4, with a range of 6.06 to 37.04% (see Table 4). In addition, the percentage of participants in the "Moderately ill" range decreased from T1 to T4, with a range of 3.70 to 29.03%. At T2, 0% of participants in the SR group were markedly ill, indicating an improvement of 9.68%. However, chi-square analyses did not reveal any significant differences between the two groups at different time points.

Intent-to-Treat Analyses

The sample size for intent-to-treat was 70. Participants' last available scores were carried forward to post-treatment (T2) and 3-month follow-up (T3). All significant findings for treatment completers were maintained in intent-to-treat analysis.

Discussion

Previous studies on CBT in high-functioning children with ASD have shown CBT to be effective in reducing anxiety when compared to a wait-list control. Our study further investigated the effects of CBT on anxiety in high-functioning children with ASD when compared with a SR program as an alternative form of treatment to evaluate the effect of different intervention programs content and structure.

Effects of CBT and SR Programs on Anxiety

Results from our study indicated that both the CBT group and SR group showed significant reductions in generalized anxiety and total anxiety symptoms at 6-month follow-up. In addition, the SR group also showed significant reductions in panic attack symptoms at 6-month follow-up. Clinician ratings of severity of anxiety on the CGI-S demonstrated an increase in the percentage of participants rated "Normal" and "Borderline" and a reduction in the percentage of participants rated "Mildly ill", "Moderately ill" and "Markedly ill" for both CBT and SR Programs. Collectively, these findings suggest that children in both CBT and SR programs experienced reduced anxiety levels based on child and clinician reports.

CBT addresses the cognitive deficiencies and distortions that may cause social and communication difficulties, behaviors, and emotions. Practical strategies, such as problem-solving skills and relaxation techniques, are integral to helping these children interact with others effectively and appropriately, thereby promoting self-regulation. The activities conducted in the SR group are forms of leisure activities. Nuelinger defined leisure activity as "a state characterized by meaningful and nonutilitarian activity" [20]. The meaningfulness of the leisure activity is good for promoting mental health even among individuals with ASD [21]. Recent evidence has shown that self-stimulation and self-injurious behaviors can be prevented by providing an alternative sensory stimulus and in this case, the leisure activity offers that possibility [18, 22]. While the SR program does not incorporate CBT-based strategies, it contains common strategies found to be effective with children with ASD, such as the use of structure and visual cues to encourage behavioral regulation. In addition, there were also opportunities to learn and practice social and pro-social skills through some of the cooperation games, facilitated by the therapists. Children in the SR program also had opportunities to learn self-help skills such as preparing a simple meal. Hence, the SR program, while not directly addressing anxiety management, can be seen as an alternative treatment. The SR program may have addressed some deficits associated with ASD and have promoted behavioral regulation and positive social skills in these children through the variety of leisure activities, thereby reducing their levels of anxiety.

The CBT and SR programs shared common elements, namely regular sessions in a structured setting, consistent therapists, social exposure, and the use of useful strategies for ASD children (e.g., visual aids and schedules). It could be possible that the mere act of incorporating these elements in sessions will serve as an effective framework in the management of anxiety in children and adolescents with ASD. Hence, community-based and school-based structured sessions incorporating the above elements may have potential benefits in managing anxiety in ASD children and adolescents, which, in turn, may reduce the need for referrals to tertiary services for specialized programs.

Strengths of the Study

Our study (to our knowledge) is the first study in Singapore and in an Asian setting thereby validating the effectiveness of CBT in the Asian cultural context. We also adapted available materials and incorporated local elements (such as using local photographs and scenarios) to develop a manualized CBT program for ASD children in Singapore. In addition, our study compared the effects of CBT to a SR group instead of a wait-list control. We also maintained one main therapist in all groups in both treatment conditions, thereby controlling for possible "therapist effect" (gender, experience, personality) [34]. Finally, dropout rates in both groups were low ($n = 3$ per group).

Limitations and Implications of the Study

Our study presented with several limitations. Firstly, although there was sufficient power to detect a statistical significance between the CBT and SR groups, our current sample size could still have been insufficient given that we compared two active treatments. Future studies with larger samples should be considered. Secondly, we did not incorporate a parent training component in our study design. This might have affected child improvements in the CBT program. Khanna and Kendall conducted a trial of CBT in typically developing children with anxiety and incorporated parent training [35]. They found that parent training may contribute to improvements in the child's global functioning. Sofronoff et al. and Chalfant et al. found that active parent involvement enhanced the usefulness of the CBT for anxiety in children with Asperger Syndrome [14, 16]. Incorporating the Parent Training component could have empowered the parents and allowed reinforcement of skills taught to the children in a more naturalistic home setting, thereby giving rise to generalization. In addition, parent involvement in CBT may be beneficial in managing parent's anxiety, transferring control from the therapist to the parent over the child's coping, communicative skills training and contingency management training. Parent Training and skills generalization are integral components of an effective CBT program, but these were missing from our CBT program. Thirdly, while our study investigated the effects of program content in intervention, we assumed the superiority of CBT compared to wait-list controls based on findings from previous studies. Hence, we did not have a wait-list control group so as to evaluate the effects of improvement in anxiety over time without active intervention. Although child participants and parents were not actively informed of group assignment till the end of the study, it was not possible to totally blind them on group assignment.

Finally, our period of follow-up was short-term up to a period of 6 months. Longer term follow-up would ascertain if gains would be maintained at a year and beyond and would also ascertain if differences between the two treatment arms (CBT and SR group) would emerge on longer term follow-up.

Despite these limitations, the present study represents the first study in Singapore and in an Asian setting on validating the effectiveness of CBT. It also adds to a small but growing number of studies on treatment options for children with ASD. Further studies could focus on understanding the effects of the various components in the CBT and SR programs to better determine the effective components in the programs. Further studies to validate the SR program would be needed to better understand the extent and nature of its benefits.

Summary

The present study examined the effects of a 16-week cognitive-behavioral therapy (CBT) program in comparison with a Social Recreational (SR) program on anxiety in children and adolescents with Autism Spectrum Disorders (ASD). Participants included 70 children (9–16 years) randomly assigned to either of the programs ($n_{CBT} = 36$; $n_{SR} = 34$). Results indicated that children in both programs showed significantly lower levels of generalized anxiety and total anxiety symptoms at 6-month follow-up. In addition, clinician ratings of severity of anxiety demonstrated an increase in the percentage of participants rated "Normal" and "Borderline" for both programs. Findings from the present study suggest that regular sessions in a structured setting, consistent therapists, social exposure and the use of autism-related strategies serve as an effective framework in the management of anxiety in children and adolescents with ASD.

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Appendix

See Table 5.

Table 5 CONSORT statement 2001 checklist

PAPER SECTION And topic	Item	Descriptor	Reported on page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").	2
INTRODUCTION Background	2	Scientific background and explanation of rationale.	3–5
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	5–7
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	8–11
Objectives	5	Specific objectives and hypotheses.	5
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	6–7
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	12
Randomization—sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	8
Randomization—allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	8
Randomization—implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	8

Table 5 continued

*PAPER SECTION*And topic	Item	Descriptor	Reported on page #
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	8
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	12–13
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	6, Fig. 1
Recruitment	14	Dates defining the periods of recruitment and follow-up.	13
Baseline data	15	Baseline demographic and clinical characteristics of each group.	6, Table 1
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	12–15, Tables 2, 3, and 4
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval).	12–15
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	NA
Adverse events	19	All important adverse events or side effects in each intervention group.	NA
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	15–17
Generalizability	21	Generalizability (external validity) of the trial findings.	16–17
Overall evidence	22	General interpretation of the results in the context of current evidence.	15–17

From Moher et al. [36]

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