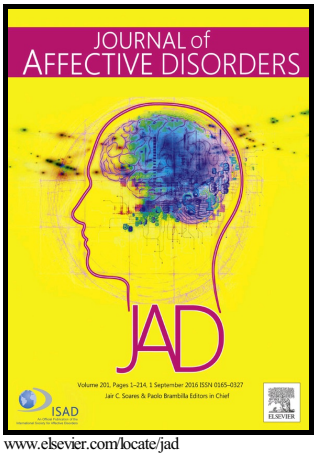

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Efficacy of an internet-based CBT program for children with comorbid High Functioning Autism Spectrum Disorder and anxiety: A randomised controlled trial

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Abstract

Background:

All trials conducted to date on BRAVE-ONLINE for youth anxiety disorders have excluded children with High Functioning Autism Spectrum Disorder (HFASD) and therefore it is unknown whether these programs might be beneficial to HFASD children. The aim of this study was to evaluate the efficacy of BRAVE-ONLINE in HFASD children with an anxiety disorder.

Methods: Forty-two HFASD children, aged 8 to 12 years, with an anxiety disorder, and their parents, were randomly assigned to either the BRAVE-ONLINE condition (NET) or a waitlist control (WLC). Diagnostic interviews and parent/child questionnaires were completed at pre-treatment, post-treatment and 3-month follow-up.

Results: At post- assessment, compared to children in the WLC condition, children in the NET condition demonstrated a significantly greater reduction in number of anxiety diagnoses, clinical severity of diagnosis, and self and parent reported anxiety symptoms, as well as significantly greater increases in overall functioning. However, loss of primary diagnosis in this sample was lower than in previous studies.

Limitations: The small sample size, coupled with attrition rates, makes it difficult to generalise the findings of the study to HFASD population and to conduct analyses regarding mediators, moderators and predictors of outcomes.

Conclusions*:* The BRAVE-ONLINE program may be useful in reducing anxiety symptoms in HFASD children, although the effects are less strong than those found in neurotypical children for a variety of reasons.

KEYWORDS:

Autism Spectrum Disorder, HFASD, child anxiety, cognitive-behavior therapy, computer, Internet.

Introduction

High Functioning Autism Spectrum Disorder (HFASD) is a neuro-developmental condition characterised by impairment in social and communication skills, restricted and repetitive patterns of behaviours, motor difficulties and sensory hypersensitivities in the context of normative intelligence (APA, 2013; Green et al., 2012; Sudholsky et al., 2008). Comorbid childhood anxiety in children with Autism Spectrum Disorder (ASD) is as high as 80% (Sukhodolosky, Bloch, Panza and Reichow, 2013), with 40% of children meeting criteria for an anxiety disorder (van Steensel et al., 2011). Understandably, comorbid anxiety can have a deleterious impact on the lives of children living with HFASD and their families, as it not only fosters its own negative consequences, it exacerbates core deficits of the disorder (Ghaziuddin, 2005; Sukholdolsky et al., 2008).

Research examining the use of cognitive behaviour therapy (CBT) for treating anxiety in children with HFASD has modified traditional CBT to better accommodate the unique profile of children with the disorder, and has now reached "probably efficacious" status according to the Chambless and Hollon (1998) criteria for empirically-validated treatments (Rudy et al., 2013). Common modifications involve increasing affective education, taking a more behavioural focus, targeting co-occurring ASD difficulties, increasing parental involvement and visual cues, and incorporating special interests (Attwood, 2008; Green & Wood, 2013).

Sofronoff, Attwood and Hinton (2005) were among the first to modify CBT for children with HFASD and anxiety, finding that children in both the child only, and the parent involved conditions demonstrated significantly greater reductions in parent-reported levels of child anxiety compared to the WLC condition at 3-month follow up (Sofronoff, Attwood, & Hinton, 2005). Since that time, there have been a number of studies investigating the efficacy of modified CBT treatment protocols for anxiety with positive results (see Chalfant, Rapee, & Carrol, 2007; Fuji et al., 2013; Lang, Regester, Lauderdale, Ashbaugh and Haring, 2010; McNally Keehn, Lincoln, Brown, & Chivara, 2013; Reaven, Blakeley-Smith, Culhane-Shelburne, & Hepburn, 2012; Reaven et al., 2009; Scarpa & Reyes, 2011; Sukhodolosky et al., 2013; Sung et al., 2011; Storch et al., 2013, 2015; Wood & Drahota, 2005; Wood et al., 2009, 2015). Furthermore, in a recent systematic meta-analytic review of modified CBT for the treatment of anxiety in children with HFASD, it was found that modified CBT was superior to control conditions with a moderate effect size, and upon removal of child reported outcomes, the effect size increased (Ung, Selles, Small and Storch, 2015).

Although it is clear that modified CBT works for anxious HFASD children, we do not know whether unmodified CBT programs for anxiety disorders might also be efficacious for this population. In the myriad of trials conducted on CBT for youth anxiety, HFASD children

have been routinely excluded, and therefore it remains unknown whether or not such programs would actually be helpful for these children. Indeed, it has been largely assumed that modifications are required for CBT anxiety programs to be efficacious, yet this has not actually been shown to be the case empirically to our knowledge. It is important to ascertain whether unmodified CBT programs might actually assist HFASD children with anxiety, as there are significantly more unmodified programs available to families, some of which are freely available. In contrast, modified CBT programs are less prolific and require specialist knowledge and training to deliver. If unmodified CBT programs are found to be efficacious for even a sub-group of HFASD children, it may reduce the significant burden on specialist agencies and allow families to more quickly, easily and affordably receive the help they require. Of particular usefulness in terms of availability, cost and convenience, is the potential for computer-based CBT programs for anxiety to be trialled with HFASD children.

Computer-based CBT programs were developed in an attempt to reach the significant number of youth who either do not seek, or seek but do not receive, appropriate health services. It is thought that up to 80% of youth with anxiety disorders do not access or utilise the available health services (Booth et al., 2004; Boyd et al., 2007; Essau, 2005; Merikangas et al., 2011; Owens et al., 2002). A number of barriers to mental health help-seeking have been put forward including; stigma, poor mental health literacy, uncertainty regarding where to access support, unable to afford support costs, believing the problem would rectify itself, wanting to work the problem on their own or with help from family or friends, being a single parent, unemployed, and residing in a rural area (Booth et al., 2004; Lawrence et al., 2015; Lin, Goering, Offord, Campbell, & Boyle, 1996; Merikangas et al., 2011; Parikh, Wasylenki, Goering, & Wong, 1996; Wang et al., 2005). Computer-based approaches circumvent many of these barriers as they can be accessed anytime, within any setting (e.g. home, work, school)

and offer a sense of privacy and confidentiality (James et al, 2007, 2013; Richardson, Stallard, & Velleman, 2010).

In addition to the advantages of computer-based CBT approaches discussed above, there are other reasons why computer-based CBT might be particularly useful and appealing to HFSAD youth. It is widely acknowledged that children with HFASD have specific interests, a frequent one of which is technology (Attwood, 2004, 2008). Thus, computerised CBT treatments may arguably increase the likelihood for success through desire for engagement, enjoyment and subsequent reduction in affective dysregulation. Furthermore, online CBT programs are highly visual, animated, entertaining, and structured, attributes that ASD experts recommend for programs of any kind targeting ASD children (Attwood, 2004; Donoghue, Stallard, & Kucia, 2011; Odom et al., 2003; Sofronoff et al., 2005). Additionally, as HFASD families have numerous competing demands, offering a program that is flexible and able to be undertaken within the family home and schedule, may remove the associated stress and difficulties that go along with attending a clinic.

For all of the above reasons, this study aimed to evaluate the efficacy of an unmodified, online CBT program for anxiety disorders (BRAVE-ONLINE) in a sample of HFASD children. Spence and colleagues (March et al, 2009; Spence, Holmes, March & Lipp, 2006; Spence et al., 2011) have systematically evaluated BRAVE-ONLINE in a series of randomised controlled trials (RCTs). In their initial RCT, Spence, Holmes, March and Lipp (2006) compared the BRAVE program delivered partially via the Internet (CLIN-NET), with clinic based delivery (CLINIC) and a WLC group for children aged 7-14 years with a diagnosis of anxiety. The CLINIC group and CLIN-NET groups both demonstrated significantly greater reductions in anxiety from pre-to-post treatment compared to the WLC, with minimal differences between the two treatments in terms of efficacy. In the second RCT, March, Spence and Donovan (2009) examined the efficacy of a fully online version of

BRAVE (NET) for children aged 7-12 years compared to a WLC. At 6-month follow-up, 75% of children in the NET group no longer met criteria for their primary anxiety diagnosis, and 60.7% were free of all anxiety diagnoses. The final RCT trialled an adolescent version of BRAVE-ONLINE (NET) compared to clinic delivery (CLIN) and a WLC, in a sample of 115 adolescents aged 12 to 18 years with an anxiety diagnosis (Spence et al., 2011). By 12-month follow-up, 78.4% of the NET group and 80.6% of the CLIN group were free of their primary anxiety diagnosis, with minimal differences between the online and clinic versions conditions in terms of efficacy.

As noted above, unmodified CBT anxiety programs, whether they be face-to-face or computer-based, have not been tested in terms of their efficacy with HFSAD children. This study sought to examine the efficacy of the BRAVE-ONLINE program for HFASD children aged 8 to 12 years with an anxiety disorder. It was hypothesised that from pre to post-treatment, NET children would demonstrate: greater remission; greater reduction in number of anxiety diagnoses, anxiety severity, anxiety symptoms, internalising behaviours; and a greater improvement in overall level of functioning, compared to WLC children. It was further hypothesised that these improvements would be maintained at 3-month follow-up.

Method

Participants

Forty-two Australian children aged between eight and twelve years (M=9.74; *SD* = 1.3) with HFASD (AS) and one of their parents (97.6% mothers, 2.4% fathers) participated in the study. Table 1 outlines the socio-demographic information for the treatment group, the waitlist control group, and the total sample. As is evident from Table 1, 36 (85.7%) of the participants were male and 6 (14.3%) were female, with the majority being born in Australia. The majority of children (81%) resided with both biological parents, and had one or more siblings (97.6%). None of the families identified as being of Aboriginal and/or Torres Strait

Islander descent and the majority were of middle to high socio-economic status. Of the sample, 29 (69%) children had a primary diagnosis of Social Anxiety Disorder (SAnD), 12 (28.6%) had Generalised Anxiety Disorder (GAD) and 1 (2.4%) had Specific Phobia (SP). The average number of anxiety diagnoses was 3.36 across the total sample, and all children met criteria for more than one anxiety disorder diagnosis. Table 2 outlines the comorbidity of the sample as a whole.

Children were recruited Australia-wide through referrals from general practitioners, mental health professionals, school guidance officers, teachers, parents and media publicity. Self-referrals were also accepted. Figure 1 outlines the flow of participants through the study. As is evident from Figure 1, 21 participants were allocated to the NET condition and 21 were allocated to the WLC condition. For inclusion in the study, children were required to hold a diagnosis of Asperger's Syndrome (AS) made by a health professional (paediatrician, psychologist, psychiatrist), with diagnoses confirmed by the Childhood Asperger Syndrome Test (CAST; Scott, Baron-Cohen, Bolton & Brayne, 2002) (see below). In addition, children were required to have a clinical diagnosis of either Separation Anxiety Disorder (SAD), SP, SAnD or GAD with a clinical severity rating (CSR) of 4 or greater according to the Anxiety Disorders Interview Scale for Children (ADIS-C/P; Silverman & Albano, 1996). To be eligible for study inclusion, children also had to be aged between 8 to 12 years, able to read and write English at a minimum age 8 years level, and have access to a computer equipped with internet access from home. A minimum diagnostic severity rating of 4, based on an 8-point clinician scale, was required, and comorbidity with other anxiety disorders and externalising disorders was permissible. Children, who were identified as meeting clinical levels of depression, dysthymia or an externalising disorder above a CSR of 5 as measured by the ADIS-C/P were not included in the study for ethical reasons and were referred elsewhere for appropriate support. Children were also excluded if they were receiving psychosocial

treatment for anxiety elsewhere, had a diagnosed learning disorder, or possessed significant intellectual or physical impairment.

Measures

For the NET group, all measures outlined below were taken at pre, post and 3-month follow-up, with the exception of the CAST (Scott, Baron-Cohen, Bolton & Brayne, 2002) and the demographic questionnaire that were only administered at pre-treatment (see below). The WLC group completed questionnaires at pre and post-treatment only.

Demographics.

Parents were required to report mother and fathers' age, gender of parent completing questionnaires, combined family income, mother and father's highest level of education, and marital status. Additionally, they were required to report information relating to their child's, age, gender, country of birth, cultural identification, year level at school, number of siblings and living circumstances.

Childhood Asperger Syndrome Test (CAST;

Scott, Baron-Cohen, Bolton & Brayne, 2002). For all participants, the CAST was used to support the parent-reported professional diagnosis of Asperger's Syndrome (AS). The CAST is a 37-item parent-report questionnaire designed to screen for high-functioning autism spectrum conditions in school-aged children. Thirty-one of the 37 items are summed to provide an overall score, with the remaining 6 items related to general development. A cut-off score of 15 or greater indicates the potential presence of AS. Using the cut-off score of 15, the CAST demonstrates a sensitivity of .88, a positive predictive value of .64 and a specificity value of .98 (Scott et al., 2002). It has been found to have a moderate to high test-retest reliability of .70 (kappa statistic).

Anxiety Disorders Interview Schedule for DSM-IV: Parent and Child Version.

Children's diagnostic status was evaluated using a telephone administration of the Anxiety Disorders Interview Schedule for DSM-IV (ADIS–C/P; Silverman & Albano, 1996). The telephone version of the ADIS-C/P has been shown to be equivalent in terms of reliability and validity and was necessary given that participants were recruited Australia-wide (Cobham, Dadds & Spence, 1998, 2010; Lyneham & Rapee, 2005). The ADIS-C/P is a semi-structured interview that allows for the identification of current anxiety disorders. Each diagnosis is given a clinician severity rating (CSR) that may range from 0 (no interference) to 8 (extreme or disabling interference), with scores of 4 (moderate interference) and above indicative of clinical impairment. As recommended by Silverman and Albano (1996), child and parent scores were combined to provide a composite diagnosis of the child's reported difficulties. Interviewers were registered psychologists with a minimum of eight hours training in the schedule and who were blind to treatment condition. All interviewers received ongoing supervision by a psychologist throughout the study. The ADIS-C/P has displayed good to excellent test-retest reliability, with kappa's rating from .61 to 1.00 and moderate to high inter-rater reliability, with kappa's ranging from .45 to 1.00 (Lyneham & Rapee, 2005; Rapee, Barrett, Dadds, & Evans, 1994; Silverman & Eisen, 1992; Silverman, Saavedra, & Pina, 2001).

The Children's Global Assessment Scale.

The Children's Global Assessment Scale (CGAS; Schaffer et al, 1983) was used to measure the child's overall level of functioning, with clinicians assigning a rating based on information gathered from the ADIS-C/P. The child is assigned a score ranging from 0 to 100, with higher scores indicating a higher level of functioning. Scores of 0-40 represent serious disability or impairment, scores of 41-60 indicate moderate disability or impairment, scores of 61-80 suggest slight disability or impairment, and scores of 81-100 indicate a normal level of functioning (Schaffer et al., 1983). The CGAS has demonstrated good inter-rater reliability (*r*

= .84) and test–retest reliability (*r* = .85; Dyrborg et al., 2000; Rey, Starling, Wever, Dossetor, & Plapp, 1995; Schaffer et al., 1983).

Child Behavior Checklist – Revised.

The Child Behavior Checklist – Revised (CBCL; Achenbach & Rescorla, 2001) was used to assess internalising behaviours. Parents were required to rate the extent to which each item was representative or characteristic of their child on a 3-point scale (0 = "not true"; 1 = "somewhat or sometimes true"; and 2 = "very true or often true"). The internalising scale (CBCL-int) consists of 32 items that are scored to produce an internalising score that may range from 0 to 64, with higher scores indicating greater internalising behaviours. The CBCL has demonstrated excellent psychometric properties, with test-retest reliability found to range from .95 to 1.00 and internal consistency estimates ranging from .78 to .97 (Achenbach & Rescorla, 2001). The reliability of the CBCL-int subscale was .88 in the current study.

Spence Children's Anxiety Scale – Child (SCAS-C; Spence, 1998) *and Parent* (SCAS-P; Spence, 1999) *Versions*. The SCAS-P and SCAS-C were used to assess child anxiety symptoms. The SCAS-C consists of 44 items while the SCAS-P comprises 38 items that are summed to produce a total score that may range from 0 to 114, with higher scores indicating greater anxiety. Children and parents are required to indicate how often the child experiences each item on a 4-point scale from 0 (never) to 3 (always). The SCAS-C and SCAS-P have been found to have excellent internal consistencies of .92 and .89 respectively (Muris, Schmidt, & Merckelbach, 2000; Spence, 1998; Spence, Barrett, & Turner, 2003). The reliability of the SCAS-C was .86 and the SCAS-P was .88 in the current study.

Satisfaction with Treatment.

Satisfaction with the program was measured with an 8-item rating scale designed by Spence, Holmes, March and Lipp (2006). The questionnaire was completed by NET children and parents at post-assessment and follow-up. Participants were requested to rate their satisfaction

with the program on a 5-point scale from 1 (not at all true) to 5 (very true). Scores were averaged to provide a mean satisfaction score, with higher scores indicating higher levels of satisfaction (Spence et al., 2006).

Procedure

Following Griffith University ethics approval, participants were recruited Australia wide through referrals from general practitioners, mental health professionals, school guidance officers and media publicity. Self-referrals were also accepted. Upon registration of interest, referrals were screened by telephone using a standard screening interview and the CAST, in order to determine eligibility for the study. Pre-assessment occurred prior to random allocation to eliminate any potential bias. Once deemed potentially eligible, participants were directed to an online information and consent page, and following consent, then went on to complete the online questionnaire package. After questionnaire completion and subsequent screening of the questionnaires, children and parents deemed likely to hold a clinical-level anxiety disorder completed the ADIS-C/P. Children who were confirmed to have both AS and a clinical-level anxiety disorder were included. All families excluded from the study were provided with appropriate referrals.

Eligible children were randomly allocated to condition (NET versus WLC) via a computer program that produced an order of inclusion in advance of the study that was unknown to the researcher assigning participants to condition. Evaluation of the NET group participants was conducted at pre-treatment, post-assessment (approximately 10-14 weeks following the commencement of treatment) and 3 month follow-up while WLC participants were assessed at times corresponding to pre-treatment and post-assessment. Post-assessment and 3-month follow-up were conducted by independent interviewers who were blind to condition and assessment time-point. After completing their post-treatment evaluations,

children in the WLC group ceased to be part of the study and were provided access to the BRAVE-ONLINE program.

Treatment Protocol / Intervention

The BRAVE -ONLINE program was developed as a transdiagnostic CBT intervention for the treatment of SAD, SAnD, SP and GAD (March et al, 2009; Spence et al., 2006, 2011). For a comprehensive review of the program, see Spence et al., (2008). The program consists of 10 child, and six parent sessions, each 60-minutes in length, that are completed weekly online via the Internet, as well as two booster sessions undertaken one and three months after completion of the program. BRAVE-ONLINE is therapist assisted in that participants receive weekly, online contact with a therapist in response to session activities, as well one short phone call midway through the program to assist with exposure hierarchy construction.

Data Analysis

Preliminary analyses using a series of chi square, ANOVA and MANOVA were conducted on the entire sample (N=42) to ensure that there were no pre-existing differences between the treatment and waitlist conditions on any of the demographic or outcome variables prior to treatment. Linear mixed model analyses were conducted with the intent to treat (ITT) sample to determine the relative change in outcome variables over time between the NET and WLC groups.

Results

Pre-Treatment Comparisons

With regard to demographic variables prior to treatment, chi-squared analyses revealed no significant differences between the groups on child gender χ^2 (1, N = 42) = 3.11, p = .184, child country of birth χ^2 (1, N = 42) = 1.11, p = .606, combined family income χ^2 (4, N = 42) = 4.58, p = .333, maternal level of education χ^2 (5, N = 42) = 1.07, p = .957, or paternal level of education χ^2 (6, N = 42) = 9.49, p = .148. Similarly, univariate analyses of

variance (ANOVAs) showed that there were no significant differences between conditions on child age $F(1, 40) = .12$, $p = .732$, $\eta^2 = .003$, mother age $F(1, 40) = .81$, $p = .375$, $\eta^2 = .02$, or father age $F(1, 39) = .01$, $p = .934$, $\eta^2 < .001$ prior to treatment.

With respect to outcome variables, the MANOVA including number of diagnoses, CSR and CGAS at pre-treatment was not found to be significant, Pillai's $F(3, 38) = .094$, $p = .285$, $\eta^2 = .094$, thus suggesting no significant pre-existing differences between the NET and WLC conditions on these variables prior to treatment. Similarly, the MANOVA including pre-treatment SCAS-C, SCAS-P and CBCL-int was not found to be significant, Pillai's $F(3, 38) = .05$, $p = .59$, $\eta^2 = .049$, suggesting no significant differences prior to treatment between the NET and WLC groups on these variables.

Outcome measures at post-assessment and 3-month follow-up

The estimated marginal means for Number of Diagnoses, CSR, CGAS, SCAS-C, SCAS-P and CBCL-INT are presented in Table 3 (pre- to post-assessment for NET and WLC groups) and Table 5 (pre- to post-assessment and 3-month follow-up for the NET group). The fixed effects for intercept and slopes and effect sizes are presented in Table 4 (pre- to post-assessment for NET and WLC groups) and Table 6 (pre- to post-assessment and follow-up for the NET group).

For the completer sample, 20% of the NET group versus 0% of the WLC group were free of their primary diagnosis at post-assessment, with 38.9% of the NET group being free of their primary diagnosis by 3-month follow-up. With respect to loss of all anxiety diagnoses (for the completer sample), 10% of the NET group versus 0% of the WLC group had lost all anxiety diagnoses by post-assessment, with 16.7% of the NET group being free of all diagnoses by 3-month follow-up. There were no significant differences between the NET and WLC groups (completer sample) at post-assessment on those free of their primary diagnosis, χ^2 (1, N=38) =4.02, p=.107 or those free of all diagnoses, χ^2 (1, N=38) =1.90, p=.488.

For the ITT sample, 19% of the NET group versus 0% of the WLC group were free of their primary diagnosis at post-assessment, with 33.3% of the NET group being free of their primary diagnosis by 3-month follow-up. With respect to loss of all anxiety diagnoses (for the ITT sample), 9.5% of the NET group versus 0% of the WLC group had lost all anxiety diagnoses by post-assessment, with 14.3% of the NET group being free of all diagnoses by 3-month follow-up. There were no significant differences between the NET and WLC groups (ITT sample) at post-assessment on those free of their primary diagnosis, χ^2 (1, N=42) =4.42, p=.107 or those free of all diagnoses, χ^2 (1, N=42) =2.10, p=.488.

With respect to number of anxiety diagnoses, there was a significant effect for time, F(1, 39.95) = 5.42, p=.025, and a significant condition by time interaction, F(1, 39.95) = 32.14, p<.001 from pre to post-treatment, as well as a significant effect for time from pre- to 3-month follow-up, F(2, 36.38) =24.75, p<.001. In terms of CSR of the primary diagnosis, there was a significant effect for time, F(1, 42.16) = 26.71, p<.001, and a significant condition by time interaction, F(1, 42.16) = 12.57, p =.001 from pre to post assessment, together with a significant effect for time from pre to 3-month follow-up, F(2, 40.93) =16.09, p<.001. Similarly, with respect to the CGAS, there was a significant effect for time, F(1, 40.23) =44.11, p<.001, and a significant condition by time interaction, F(1, 40.23) = 18.56, p <.001 from pre-assessment to post-assessment, as well as a significant effect for time from pre to 3-month follow-up, F(2, 38.51) = 33.53, p <.001. The results for the SCAS-C and SCAS-P painted a similar picture. There was a significant effect for time, F(1, 32.49) =77.03, p<.001, and a significant condition by time interaction, F(1, 32.49) =4.83, p=.035 for the SCAS-C from pre to post-assessment as well as a significant effect for time from pre to 3-month follow-up, F(2, 28.46)=38.95, p<.001. Similarly, there was significant effect for time, F(1, 36.25) =33.10, p<.001, and a significant condition by time interaction, F(1, 36.25) =4.49, p=.041 from pre to post-assessment for the SCAS-P as well as a significant effect for time

from pre to 3-month follow-up, F(2, 33.92)=18.99, p<.001. Finally, with respect to the CBCL-int, there was a significant effect for time, F(1, 36.10) =35.59, p<.001, and a significant condition by time interaction, F(1, 36.10) =7.18, p=.011 from pre-assessment to post-assessment, together with a significant effect for time from pre to 3-month follow-up, F(2, 33.88) =25.85, p<.001. Inspection of Tables 4, 5 and 6 indicate that the NET group showed a significantly greater reduction in number of anxiety diagnoses, CSR, CGAS, SCAS-C, SCAS-P, and CBCL-int from pre to post treatment compared to the WLC group, with treatment effects being maintained at 3-month follow-up.

Session Completion

At the post-assessment time point, parents in the NET group had completed a mean of 4.86 (SD=1.85) out of six sessions, with 71.5% completing Session 5 (the exposure session) and 42.9% completing all six sessions. At the 3-month follow-up time point, parents had completed a mean of 5.24 (SD=2.21) out of six sessions. There were no differences in the number of completed sessions at post-assessment and follow-up, with 71.5% of parents completing Session 5 (the exposure session) and 42.9% all six sessions at 3-month follow-up.

At the post-assessment time point, children in the NET group had completed a mean of 6.71 (SD=2.99) out of 10 sessions, with 81% completing Session 5 (the exposure session) and 19% completing all 10 sessions. At the 3-month follow-up time point, children had completed a mean of 7.38 (SD= 3.60) out of 10 sessions. At follow-up, again 81% of children had completed Session 5, and 38% had completed all 10 sessions.

Treatment Satisfaction

Satisfaction data were collected from 14 children and 18 parents of the NET group. Children and parents reported moderate levels of satisfaction following treatment (child ratings: *M* = 3.03, *SD* = 1.03; parent ratings: *M* = 3.58, *SD* = 0.86).

Discussion

The aim of this study was to evaluate the efficacy of an Internet-based cognitive-behavioural therapy (CBT) intervention (BRAVE-ONLINE) for the treatment of child anxiety disorders in children with HFASD. Results indicated that there were no significant differences between the NET and WLC groups regarding loss of primary diagnosis at post-assessment. However, compared to children in the WLC group, children in the NET condition experienced significantly greater reductions in number of diagnoses, clinical severity of primary diagnosis, global assessment of functioning, anxiety symptoms and internalising behaviours, with treatment gains being maintained at 3-month follow-up.

Turning first to the results concerning the number of children free of their primary diagnosis. In the current study, 20% and 38.9% of NET children (in the completer sample) were free of their primary diagnosis at post-assessment and 3-month follow-up respectively. This can be compared to the March et al (2009) study that examined the same BRAVE-ONLINE program with similarly aged neurotypical children, where 30% and 75% of children were free of their primary diagnosis at post-assessment and 6-month follow-up respectively. On a broader level, modified CBT programs have yielded remission rates ranging from no significant differences in loss of primary diagnosis (McConachie et al., 2014), to 71.4% (Chalfant et al., 2007; Fuji et al., 2013) at post-treatment. Thus, it is clear that the results are substantially less impressive for the present study, with a number of possible explanations for why this might be so.

One explanation concerns treatment compliance and the length of time taken to complete treatment. In the current study, 19% and 38% of children had completed all 10 sessions at post-assessment and 3-month follow-up respectively, compared to 33.3% and 62% in the March et al (2009) study. Similarly, 42.9% of parents had completed all 6 sessions at post-assessment and 3-month follow-up, compared to 60% and 72.3% in the March et al

(2009) study. Thus, HFASD families appeared to complete fewer sessions that than their neurotypical counterparts and therefore it is perhaps not surprising that their remission rates were lower. The substantially lower compliance rates in the current study may be due to the myriad of difficulties faced by families with a HFASD child. It is likely that the intensified strain experienced by these families, places greater stress on the individual and the family system, perhaps making it more difficult to comply with a largely self-help program, and to apply and generalise the strategies learned.

A second reason for the lower remission rates in the present study may be due the difference in follow-up time points between March et al (2009) and the current study, with the March et al (2009) study employing a 6-month follow-up and the present study employing on a 3-month follow-up. Our 3-month follow-up point may not have been long enough for treatment effects to become evident. In contrast, a 6- or 12-month follow-up point would allow sufficient time for skill application and generalisation, and potentially the subsequent loss of primary diagnosis.

Despite the rather lack lustre results for loss of diagnosis, there were significantly greater reductions for the NET group compared to the WLC group on all other measures over time, suggesting that the program was effective in reducing anxiety and improving overall level of functioning. These findings are consistent with those of the March et al (2009) study, where at post-assessment, children in the NET group showed significantly greater improvement in clinical severity of primary diagnosis, global assessment of functioning, parent-reported levels of anxiety and internalising behaviours compared to the WLC. Similarly, with respect to satisfaction, both children and parents reported moderate levels of satisfaction, consistent with those reported in the March et al (2009) study of neurotypical children. Thus, it would seem that significant improvement in anxiety and general functioning

occurred as the result of treatment, despite remission rates being lower, and that both parents and children were largely satisfied with the program.

Strengths, Limitations and Future Research Directions

Despite the strengths of this study, there were also a number of limitations. First, although the CAST was included as a check to ensure the integrity of the HFASD diagnosis given by a paediatrician, it is not considered the gold standard in HFASD diagnosis. Future research should ensure that the ADOS-2 (Lord et al., 2012), frequently considered the gold standard in ASD diagnosis, is used to determine diagnostic status. Additionally, inter-rater reliability of the ADIS-C and ADIS-P were not assessed and is noted as a limitation of the study that should be addressed in future research. Furthermore, the study was pilot in nature and therefore had a somewhat small sample size. Increasing the sample size would enable investigation of predictors, mediators and moderators of treatment outcome, which would allow determination of which particular HFASD children might benefit from unmodified online CBT for anxiety and the mechanisms through which this might occur. Potential predictors / moderators of treatment outcome might include presence of another child with ASD or psychopathology, parental and family stress, age of child, and number of children in the family. Future research should employ larger sample sizes so that potential predictors and mechanisms of change can be investigated.

Another limitation involves the substantial attrition across the course of the study and the less-than-perfect session completion rates evident, both of which bring up a number of issues. First, the fact that some children were lost to follow-up and others failed to complete all sessions, is likely to be at least in part due to the fact that families with a HFASD child have many competing demands and as a result can be quite chaotic. These issues can be problematic for face-to-face treatment as well, but are likely to be even more problematic when therapy is conducted online where it is easier to 'put off' sessions more easily.

Interestingly, the number of sessions completed was not markedly different from that found by March et al (2009), with both child and parent participants in the present study completing approximately one less session each than the neurotypical children in the March et al (2009) study at post-assessment. Indeed, non-completion of sessions is problematic for internet-programs and has been noted in all studies conducted on BRAVE-ONLINE to date (March et al., 2009; Spence et al., 2008; Spence et al., 2011). Sessions are designed to be interesting and stimulating for children and parents. However, unassisted completion of sessions still requires significant motivation and organisation. Thus, for both neurotypical and HFASD children, it is important for future research to determine family and child characteristics that predict both session completion and treatment outcome. Equally, research investigating not only session compliance but also compliance with homework (and particularly exposure) exercises in relation to treatment outcome will also be important for both neurotypical and HFSAD children engaged in online therapy for anxiety. It may be that it is not so much the number of session completed that is important to treatment outcome, but rather the homework (and particularly exposure homework) that is completed. Future research should investigate the potential roles of session completion and homework completion on treatment outcome.

Another limitation to the study is the absence of a face-to-face CBT comparison group, making it difficult to conclude whether it was the unmodified nature of the program, or the online delivery of the program that resulted in the effects found. Future research should include a face-to-face condition to allow for this comparison. Furthermore, although this study was an important first step in testing the usefulness of unmodified, online CBT for anxiety in children with HFASD, it will be important for future research to extend upon this study by determining the relative efficacy of modified versus unmodified online, CBT for anxiety in children with HFASD.

Finally, the absence of a control group at 3-month follow-up, made it impossible to determine whether improvements evident at the 3-month assessment point were the result of natural recovery or the effects of treatment and highlight another limitation. It is suggested that future research extends the wait-list period past the post-treatment point and onto follow-up periods to allow better determination of whether further improvements are being made due to treatment or whether they are simply due to the passage of time. Furthermore, the 3-month follow-up point may not have been long enough to determine possible positive effects of the program. Thus, future research should include employ 6- and 12-month follow-up points to better assess the long-term usefulness of the program.

Conclusions and Clinical Implications

Given the significant rates of anxiety disorder in children with HFASD and the deleterious impact on both the individual and their families, it is essential to explore the efficacy of readily available standardised CBT interventions for this population. The results of this small, pilot RCT provide preliminary evidence that unmodified standardised CBT programs for the treatment of anxiety disorders in children can produce statistically significant reductions in anxiety for HFASD children with anxiety. Although these results require replication, they suggest promise in broadening available, cost effective and easily accessible standardised CBT intervention options for the successful treatment of anxiety in individuals with HFASD and their families.

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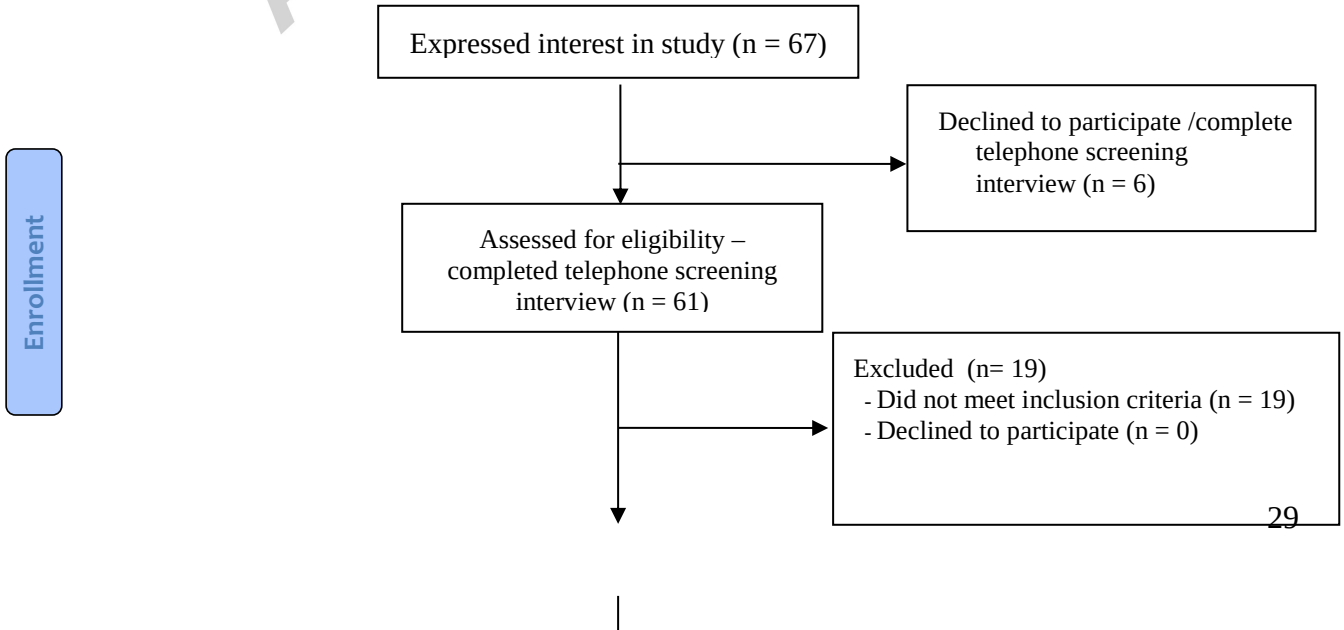

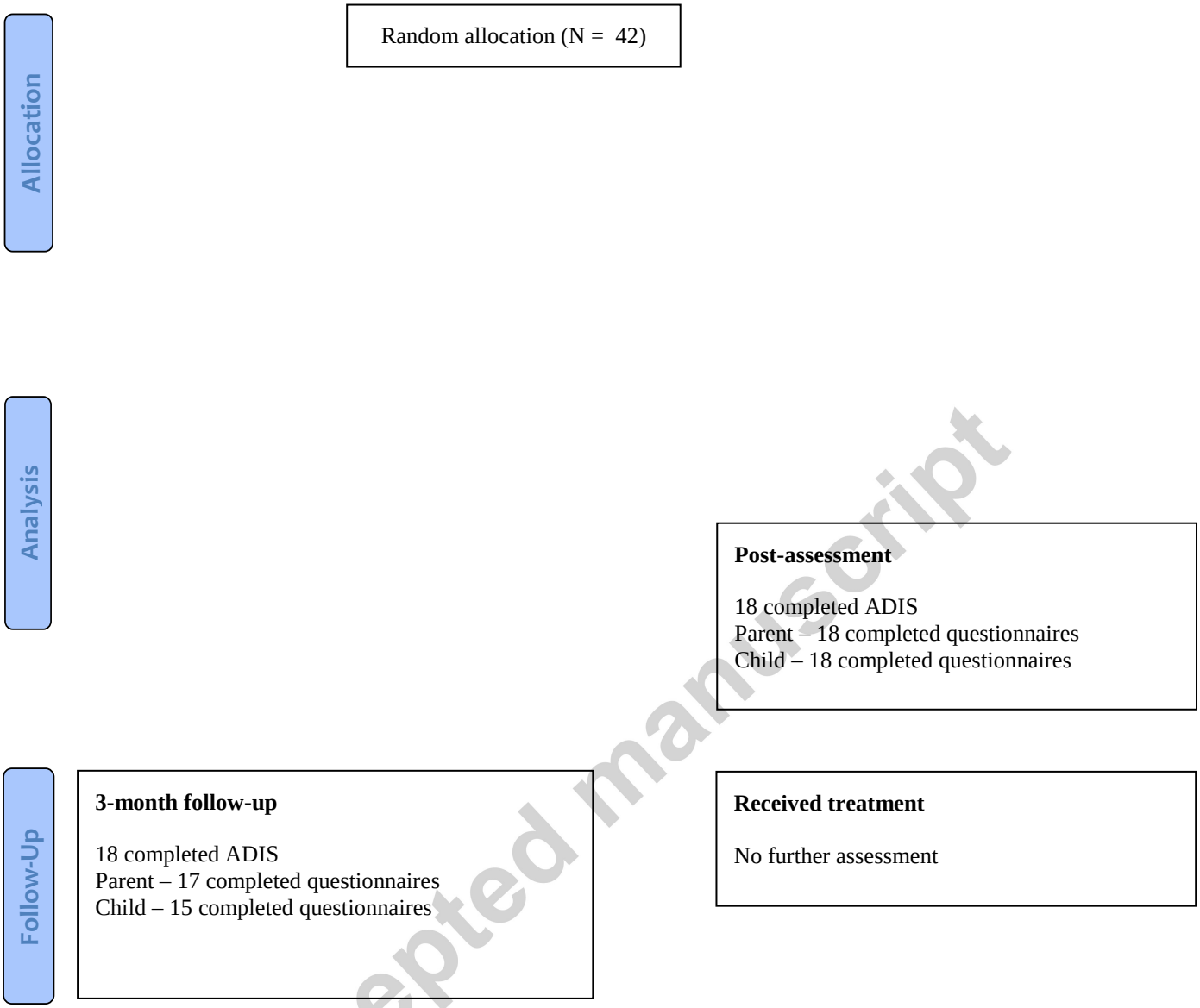

Figure 1. CONSORT Diagram

Table 1 *Pre-treatment Socio-demographic Information (N=42)*

Demographic	Treatment (n = 21)	Waitlist (n = 21)	Total (N = 42)
Gender (%)			
Female	23.8	4.8	14.3
Male	76.2	95.2	85.7
Age in years (Mean)			
Child	9.81	9.67	9.74
Mother	40.86	39.62	40.24
Father	42.24	42.40	42.32

Combined family income (%)			
<AU $40,000	9.5	4.8	7.1
AU $41,000- AU $60,000	14.3	9.5	11.9
AU $61,000- AU $80,000	19.0	19.0	19.0
AU $81,000- AU $100,000	4.8	28.6	16.7
>AU$100,000	52.4	38.1	45.2
Highest level of education (%)			
Mother			
Postgraduate University Degree	28.6	19.0	23.8
Undergraduate University Degree	9.5	9.5	9.5
TAFE or Apprenticeship	42.9	42.9	42.9
Completed Year 12	9.5	19.0	14.3
Completed Year 10	9.5	9.5	9.5
Highest level of education (%)			
Father			
Postgraduate University Degree	19	9.5	14.3
Undergraduate University Degree	23.8	33.3	28.6
TAFE or Apprenticeship	42.9	42.8	42.9
Completed Year 12	0	14.3	7.1
Completed Year 10	9.5	0	4.8
Did Not Complete Year 10	4.8	0	2.4
Child's country of birth (%)			
Australia	85.7	95.2	90.5
United Kingdom	9.6	0	4.8
Scotland	0	4.8	2.4
United States of America	4.8	0	2.4

Table 2 *Pre-treatment Diagnostic Information for total sample according to condition*

	Treatment N=21		Waitlist N=21	
Mean severity of primary anxiety diagnosis	6.62		6.76	
Mean number of anxiety disorders	3.38		3.33	
CGAS rating	48.52		46.05	
	N	% of children	N	% of children
Primary Anxiety Diagnosis			15	

Social Anxiety Disorder	14	66.7	5	71.4
Generalised Anxiety Disorder	7	33.3	1	23.8
Specific Phobia - Dark	0	0		4.8
Secondary Anxiety Diagnosis			4	
Social Anxiety Disorder	6	28.6	11	19.0
Generalised Anxiety Disorder	12	57.1	2	52.4
Separation Anxiety Disorder	1	4.8	0	9.5
Specific Phobia – Blood	1	4.8	2	0
Specific Phobia – Dark	1	4.8	1	9.5
Specific Phobia – Insects	0	0	1	4.8
Specific Phobia - Thunderstorms	0	0		4.8

Note: Severity = 0 (none) to 8 (severe), CGAS = Children's Global Assessment Scale

Table 3 *Estimated marginal means and standard errors for Outcome Variables from pre- to post-assessment*

		NET			WLC		
	Time	*M*	*SE*	*d*	*M*	*SE*	*d*
Number of							
Diagnoses	Pre	3.38	.26		3.33	.26	
	Post	1.79	.26	.95	4.00	.27	-.39
CSR	Pre	6.62	.31		6.76	.31	
	Post	4.10	.31	1.25	6.29	.33	.23
CGAS	Pre	48.52	1.65		46.05	1.65	
	Post	62.10	1.68	-1.26	48.94	1.75	-.26
SCAS-C	Pre	39.10	2.98		38.48	2.98	
	Post	23.77	3.20	.77	29.29	3.06	.47
SCAS-P	Pre	36.95	3.21		36.62	3.21	
	Post	23.80	3.32	.62	30.55	3.32	.29

CBCL-INT	Pre	22.62	2.19		25.91	2.19	
	Post	12.91	2.27	.67	22.22	2.27	.26

Note: Effect sizes were calculated from Pre to Post within condition.

Table 4 *Effects for NET and WLC for Outcome Variables from pre- to post-assessment*

	B	SE	ES
Number of Diagnoses			
Intercept			
WLC baseline	3.38***	.26	4.06
NET-WLC	-.05	.35	-.06
Slope pre to post			
WLC slope	-1.60***	.28	-1.92
NET-WLC slope	2.26***	.40	2.72
Random Effects			
Level 1 residual variance		.73	
Level 2 residual variance		-.04	
CSR			
Intercept			
WLC baseline	6.62***	.31	6.23
NET-WLC	.14	.43	.14
Slope pre to post			
WLC slope	-2.52***	.40	-2.37
NET-WLC slope	2.05***	.58	1.93
Random Effects			
Level 1 residual variance		1.39	
Level 2 residual variance		-.26	
CGAS			
Intercept			
WLC baseline	48.52***	1.65	9.08
NET-WLC	-2.48	2.33	-.46
Slope pre to post			
WLC slope	13.58***	1.72	2.54
NET-WLC slope	-10.69***	2.48	-2.00
Random Effects			
Level 1 residual variance		29.24	

Level 2 residual variance	-.66		

* p<.05; **p<.01; ***p<.001 *(continued)*

Note: Effect sizes were calculated as estimated fixed effects divided by the square root of the sum of the two variance components

	B	SE	ES
SCAS - C			
Intercept			
WLC baseline	39.10***	2.98	4.54
NET-WLC	-.62	4.22	-.07
Slope pre to post			
WLC slope	-15.33***	2.09	-1.78
NET-WLC slope	6.14*	2.79	.71
Random Effects			
Level 1 residual variance		52.79	
Level 2 residual variance		21.41	
SCAS - P			
Intercept			
WLC baseline	39.95***	3.21	4.10
NET-WLC	-.33	4.54	-.03
Slope pre to post			
WLC slope	-13.15***	2.36	-1.35
NET-WLC slope	7.08*	3.34	.73
Random Effects			
Level 1 residual variance		73.08	
Level 2 residual variance		21.96	
CBCL - INT			
Intercept			
WLC baseline	22.62***	2.19	3.41
NET-WLC	3.29	3.10	.50
Slope pre to post			
WLC slope	-9.71***	1.59	-1.47
NET-WLC slope	6.02*	2.25	.91
Random Effects			
Level 1 residual variance		33.48	
Level 2 residual variance		10.42	

* p<.05; **p<.01; ***p<.001 *(continued)*

Note: Effect sizes were calculated as estimated fixed effects divided by the square root of the sum of the two variance components.

Table 5 *Estimated marginal means and standard errors for Outcome Variables from pre- to post-assessment and 3-month follow-up*

		NET		
	Time	*M*	*SE*	*d*
Number of Diagnoses	Pre	3.38	.21	
	Post	1.77	.22	
	3-mth	1.46	.23	1.91
CSR	Pre	6.62	.45	
	Post	4.11	.46	
	3-mth	3.37	.48	1.54
CGAS	Pre	48.52	1.89	
	Post	62.10	1.92	
	3-mth	67.12	2.01	-2.08
SCAS-C	Pre	39.10	2.78	
	Post	23.40	2.94	
	3-mth	22.10	3.01	1.28
SCAS-P	Pre	36.95	3.29	
	Post	23.89	3.39	
	3-mth	21.07	3.49	1.03
CBCL-INT	Pre	22.62	2.07	
	Post	12.95	2.13	
	3-mth	11.86	2.20	1.10

Note: Effect sizes were calculated from Pre to 3-month within condition.

Table 6 *Effects for NET Outcome Variables from pre- to post-assessment and 3-month follow-up*

	B	SE	ES
Number of Diagnoses			
Slope pre to post			
NET pre to 3-month	-1.92***	.31	-2.53
NET pre to post	-1.62***	.27	-2.13
Random Effects			
Level 1 residual variance		.04	
Level 2 residual variance		.94	
CSR			
Slope pre to post			
NET pre to 3-month	-3.25***	.62	-1.52
NET pre to post	-2.51***	.53	-1.18
Random Effects			
Level 1 residual variance		.40	
Level 2 residual variance		4.17	
CGAS			
Slope pre to post			
NET pre to 3-month	18.59***	2.45	1.94
NET pre to post	13.58***	1.96	1.42
Random Effects			
Level 1 residual variance		17.09	
Level 2 residual variance		74.74	
SCAS-C			
Slope pre to post			
NET pre to 3-month	-17.00***	2.43	-1.02
NET pre to post	-15.70***	1.84	-0.95
Random Effects			
Level 1 residual variance		114.15	
Level 2 residual variance		162.34	

* p<.05; **p<.01; ***p<.001 *(Continued)*

Note: Effect sizes were calculated as estimated fixed effects divided by the square root of the sum of the two variance components.

	B	SE	ES
SCAS-P			
Slope pre to post			
NET pre to 3-month	-15.88***	3.02	-0.82

NET pre to post	-13.07***	2.23	-0.68
Random Effects			
Level 1 residual variance		145.62	
Level 2 residual variance		227.14	
CBCL-INT			
Slope pre to post			
NET pre to 3-month	-10.76***	1.87	-0.88
NET pre to post	-9.67***	1.38	-0.79
Random Effects			
Level 1 residual variance		58.76	
Level 2 residual variance		90.02	

* p<.05; **p<.01; ***p<.001
Note: Effect sizes were calculated as estimated fixed effects divided by the square root of the sum of the two variance components.

Highlights

- Anxiety is often comorbid with high functioning autism spectrum disorder (HFASD)
- Prior research has trialled modified CBT programs for anxiety in HFASD children
- This study investigates unmodified internet-based CBT for anxiety in HFASD children
- Significant reductions in anxiety and internalising symptoms were demonstrated
- Significant increases in global functioning were also shown