The Efficacy of a Group-Based, Disorder-Specific Treatment Program for Childhood GAD – A randomized Controlled Trial

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Abstract

Objective. The majority of treatment programs for children with generalised anxiety disorder (GAD) are transdiagnostic in nature and do not target the specific cognitive factors argued to be integral to the disorder. The aim of this study was to provide a preliminary examination of a disorder-specific treatment program for children with GAD that employed strategies targeting underlying cognitive factors. ***Methods.*** Forty-two children with a primary diagnosis of GAD, aged between 7 and 12 years, and their parents, were randomly assigned to either a treatment (TX) or waitlist (WLC) condition. Clinical diagnostic interviews as well as parent and child questionnaires were completed at pre- and post-assessment for both conditions, and at 3-month follow-up for the TX group. ***Results.*** For the completer analyses at post-treatment, 52.9 % of children in the TX group compared to 0% in the WLC group were free of their primary GAD diagnosis. Compared to the WLC children, TX children demonstrated a greater reduction in clinical severity, greater improvement in overall functioning, and held fewer clinical diagnoses. TX children also reported greater reductions in worry and greater improvement in quality of life compared to WLC children. By 3-month follow-up, 100% of children in the TX group were free of their GAD diagnosis, 50% were free of all diagnoses, and the gains made on all other variables were maintained or improved upon (with the exception of positive beliefs about worry). ***Conclusions.*** A disorder-specific treatment program for children with GAD is effective in treating this chronic and disabling disorder.

KEYWORDS: Generalised anxiety disorder; treatment; cognitive-behaviour therapy; child psychopathology; anxiety.

Highlights

- A disorder-specific treatment program for children with GAD was developed
- Treatment consisted of 10 child sessions and 7 parent sessions, each 1.5 hours long
- Improvements in child GAD diagnostic status, symptoms, and comorbidity were found
- At post 52.9% of children in the treatment group no longer met criteria for GAD
- At 3-month follow-up, 100% of children in the treatment group were GAD-free
- At 3-month follow-up, 50% of children in the treatment group were diagnosis free

Generalised Anxiety Disorder (GAD) is a chronic and pervasive condition characterised by excessive and uncontrollable worry about numerous topics (APA, 2000). Unfortunately, children are not exempt from being afflicted with GAD, and typically worry about a wide range of issues including school work, performance based activities, the health/safety of themselves and significant others, the future, friendships and worldly affairs (e.g., war, natural disasters) (Albano & Hack, 2004; Dugas & Robichaud, 2007). In addition, children with GAD also experience severe perfectionism and sleep issues (Robin et al., 2006). Although perfectionism and sleep problems are commonly reported by children suffering with other forms of anxiety, there is some evidence to suggest that children with GAD hold stronger perfectionistic beliefs and have more sleep problems than children with other anxiety disorders (Robin et al., 2006).

Although prevalence estimates for youth GAD are difficult to ascertain and vary widely across epidemiological studies, the research suggests point prevalence rates of 0.47% to 5.9% (Anderson, Williams, McGee, & Silva, 1987; Benjamin, Costello, & Warren, 1990; Bowen, Offord, & Boyle, 1990; Ford, Goodman, & Meltzer, 2003; Lewinsohn, Hops, Roberts, Seeley, & Andrews, 1993; McGee et al., 1990), six month prevalence rates of approximately 2.8% (Breton et al., 1999), and lifetime prevalence rates of 0.4% to 5.7% (Essau, Conradt, & Petermann, 2000; Kessler et al., 2005; Lewinsohn et al., 1993; Wittchen, Zhao, Kessler, & Eaton, 1994).

Although some children with anxiety may simply ‘grow out of it’, the majority of anxious children (especially those with GAD) do not, and if left untreated, clinical-level anxiety can lead to significant difficulties later in life (Cartwright-Hatton, 2013). Indeed, GAD has been associated with a number of problematic consequences for children including difficulty concentrating at school, disrupted sleeping patterns, nervous habits (such as nail biting or skin picking), academic difficulties, and school refusal/social withdrawal due to decreased self-confidence and ostracism from peers

(Albano & Hack, 2004). Thus, GAD is a significant problem in children, and warrants empirical investigation.

Within the literature, research has demonstrated that cognitive factors such as intolerance of uncertainty (IU), positive and negative beliefs about worry (PBW and NBW), negative problem orientation (NPO) and cognitive avoidance (CA) are particularly important in the development and maintenance of pathological worry and GAD in adults (Dugas & Robichaud, 2007). *Intolerance of uncertainty (IU)* is a dispositional characteristic that originates from a set of negative beliefs about uncertainty and its consequences (Dugas & Robichaud, 2007). *Problem orientation* is a motivational process that refers to the behavioural, cognitive and emotional variables that characterise an individual's knowledge and appraisal of beliefs about, and expectancies relating to, the occurrence of problems and his or her ability to solve them (D'Zurilla & Nezu, 1999). Individuals with a *negative problem orientation (NPO)* do not lack the ability to solve problems, but rather lack confidence in their ability to do so because they see problems as difficult and threatening (D'Zurilla & Nezu, 1999). Individuals who excessively worry may also hold a number of metacognitive beliefs about worry including positive and negative beliefs about worry (PBW and NBW). Broadly speaking, metacognition refers to ‘thinking about thinking’ and involves an individual’s knowledge, appraisal, and control of his/her thought processes (Bacow, Pincus, Ehrenreich, & Brody, 2009). NBW centre around the negative mental and physical impact of uncontrollable worry (Wells, 1997), whereas, PBW centre around the utility of worry as a coping strategy (Wells, 1997). Finally, *cognitive avoidance* (CA) refers to those strategies (whether automatic or purposeful) that lead to the avoidance and/or suppression of unwanted mental content.

There is preliminary yet accumulating evidence, that children who have a tendency to excessively worry, also have difficulty tolerating uncertainty, have a negative problem orientation, attempt to avoid threatening cognitive stimuli and hold

negative beliefs about worry (Bacow, May, Brody, & Pincus, 2010; Bacow et al., 2009; Barahmand, 2008; Fialko, Bolton, & Perrin, 2012; Fisak, Mentuccia, & Przeworski, 2013; Holmes, Donovan, Farrell, & Hearn, Under Review; Holmes, Donovan, & Farrell, Under Review; Laugesen, Dugas, & Bukowski, 2003; Payne, Bolton, & Perrin, 2011). In the adult literature, PBW have been found to be associated with GAD and worry, but compared to NBW, PBW is not as specific to GAD and worry as NBW is (Bacow et al., 2010; Bacow et al., 2009; Dugas & Robichaud, 2007; Fialko et al., 2012; Holmes, Donovan, Farrell, et al., Under Review; Holmes, Donovan, & Farrell, Under Review).

Looking at the treatment of GAD in adults, there appears to be two prominent research camps; that of Dugas and colleagues, and the other by Wells and colleagues. The treatment studies conducted by Dugas and colleagues generally included worry awareness training (to identify those problems amenable to problem-solving), uncertainty recognition (to understand that uncertainty is inevitable in daily life, and that one has to learn to cope with uncertainty), re-evaluation of the usefulness of worry (for problematic positive beliefs about worry), problem solving training (for problems that are amenable to problem solving), and cognitive exposure (for those problems that cannot be solved, but rather must be tolerated because of their uncertainty, and to counteract cognitive avoidance) (Dugas et al., 2010; Dugas et al., 2003). Whilst the studies conducted by Wells and colleagues utilised MCT, which focusses on psychoeducation about the metacognitive model of pathological worry, discussion and modification of PBW, NBW and CA, and relapse prevention (Wells & King, 2006; Wells et al., 2010). Collectively, these programs have been found to be particularly efficacious, with remission rates between 60% and 87.5% (Dugas et al., 2010; Dugas et al., 2003; Wells & King, 2006). In their study, Wells et al., (2010) found that 100% of their sample was free of their primary diagnosis of GAD following treatment. However, the majority of treatment interventions aimed at child anxiety disorders (including

GAD) have involved a transdiagnostic Cognitive Behaviour Therapy (CBT) approach, where children with a variety of anxiety diagnoses are treated with the same CBT program protocol. Transdiagnostic programs are based on evidence suggesting that there are a number of cognitive and/or behavioural maintenance processes that are shared across the various anxiety disorders and typically include strategies aimed at emotional education, coping skills training, cognitive restructuring and graded in-vivo exposure (Mansell, Harvey, Watkins, & Shafran, 2009).

Research has shown that transdiagnostic CBT interventions delivered in a group or individual format, with or without parental involvement, are effective in treating children and adolescents with a range of anxiety disorders including GAD (James, Soler, & Weatherall, 2007, 2013; Silverman, Pina, & Viswesvaran, 2008). Collectively, studies have found that between 50% to 80% of youth with anxiety disorders receiving CBT show clinical levels of improvement (Cartwright-Hatton, Roberts, Chitsabesan, Fothhergill, & Harrington, 2004; Hudson, 2005; Ishikawa, Okajima, Matsuoka, & Sakano, 2007; James et al., 2007; March, Spence, & Donovan, 2009). Whilst the evidence suggests favourable outcomes for some, approximately 20% to 50% of young people continue to experience clinical levels of anxiety following treatment (Compton, Burns, Egger, & Robertson, 2002). In the case of GAD, a potential reason for the less than optimal remission rates, may be that transdiagnostic CBT approaches do not address the underlying cognitive causal and maintaining factors that have been shown empirically to be associated with GAD. Thus, despite the practical advantages of transdiagnostic CBT programs in terms of time and cost efficiency, there is an argument for disorder-specific treatment programs that allow clinicians to target the symptoms and processes unique to GAD.

Based on a review of the literature, only five studies to date have specifically examined the treatment (either transdiagnostic or disorder-specific) of GAD in youth. Of these, only two involved disorder-specific programs targeting the cognitive variables

associated with GAD, and only one of these two studies involved children under the age of 12 years. The other three studies tested programs that were transdiagnostic in nature.

Turning first to the three studies employing a transdiagnostic treatment approach. Using a case series design (*n*=4), two studies by Eisen and Silverman (1993, 1998) investigated the effectiveness of prescriptive treatments (i.e., psychoeducation, cognitive restructuring and graded exposure) versus non-prescriptive treatments (i.e., relaxation training focusing on a somatic conceptualisation of anxiety) with children diagnosed with Overanxious Disorder, aged 6 to 15 years. Although children improved in both treatment conditions, participants generally reported greater improvements in the prescriptive condition compared to the non-prescriptive condition. In another case series design of four adolescent females (aged 14 and 16 years), Waters et al., (2008) developed an intervention that incorporated psychoeducation about worry and anxiety, breathing and relaxation, cognitive restructuring, graded exposure to worry-provoking situations and interpersonal skills training (Waters et al., 2008). Overall, it was found that treatment was effective, with gains being maintained at 3-month follow-up (Waters et al., 2008).

As noted above, only two studies investigating youth with a primary diagnosis of GAD have targeted the cognitive variables implicated in the aetiology and maintenance of the disorder. Both Payne et al., (2011) and Leger et al., (2003) developed CBT programs based on the Dugas model of worry (Dugas, Gagnon, Ladouceur, & Freeston, 1998) that included worry awareness training, planned exposure to uncertainty, modification of dysfunctional beliefs about worry, modified problem-solving training, imaginal exposure to unpleasant images/worries and relapse prevention. The young children in both studies received individual therapy and there were no designated number of sessions. In their case series design of seven adolescents (aged between 16 and 18 years), Leger and colleagues (2003) found that at post treatment, three participants no longer met diagnostic criteria for GAD, two experienced

moderate reductions in the severity of their GAD diagnosis (but still met clinical criteria), and one participant remained unchanged. At 12-month follow-up, treatment gains were maintained for children who had recovered at post, and were partially maintained for those who demonstrated a reduction in GAD severity. Children completed on average 13.2 sessions. Payne and colleagues (2011) sought to replicate the findings produced by Leger et al., (2003) in a case series study of 16 young people aged 7 to 17 years, whereby therapy was terminated when the young person displayed significant improvements in their GAD symptoms or when they had completed 15 sessions (whichever came first). Overall, it was found that treatment was effective, with 81% of their sample no longer meeting diagnostic criteria for GAD from pre- to post-treatment and 59% no longer met criteria for their co-morbid anxiety diagnoses from pre- to post-treatment. Longer-term follow-up however was not conducted. The number of sessions that the children and youth received ranged from 5 to 15, with a mean of 9.69 sessions.

The Payne et al., (2011) and Leger et al., (2003) studies provide preliminary support for the efficacy of interventions for youth GAD that focus on the cognitive variables associated with the aetiology and maintenance of the disorder. However, only the Payne et al., (2011) study involved children under the age of 12 years, and both the Payne et al., (2011) and Leger et al.,(2003) studies used a case series design which has limited validity, reliability and generalisability. Furthermore, despite being based on the Dugas model of worry (Dugas et al., 1998; Dugas & Robichaud, 2007), neither study measured the cognitive constructs they purported to target in order to determine whether there was change in these variables following treatment. Finally, the treatment protocols used in these two studies were not standardised, and there were no set number of sessions completed by participants.

The present study sought to improve upon the studies conducted to date by conducting a randomised control trial (RCT) aimed at assessing the efficacy of a

treatment program targeting the cognitive variables of IU, NBW, NPO and CA, for children aged 7 to 12 years with a primary diagnosis of GAD.

There were important reasons for the present study's focus on developing and testing a GAD-specific program. Although there is little evidence to suggest that children with a primary diagnosis of GAD respond less favourably to transdiagnostic CBT than children with other anxiety disorders, between 30-50% of children with an anxiety disorder fail to demonstrate clinical levels of improvement following transdiagnostic CBT. It may well be that the less than perfect remission rate evidenced by transdiagnostic CBT programs is due to their failure to address disorder-specific symptoms and maintaining factors. In the case of GAD, such elements include worry, sleep issues, perfectionism, IU, CA, NBW and NPO. To date, none of these factors are targeted in transdiagnostic programs. Furthermore, a purely cognitive program addressing the aforementioned GAD-specific symptoms and maintaining factors has never been tested with a child population, despite being extensively tested with adults. Indeed, it is important to note that just because transdiagnostic CBT programs for child anxiety disorders are efficacious, it does not mean that we should therefore abandon our efforts to improve upon, or test alternatives to them. If it can be shown that children can in fact respond favourably to a purely cognitive program addressing GAD-specific symptoms and maintaining factors, it may go some way towards further improving treatment programs for this population.

Therefore, it was hypothesised that compared to children in the waitlist control (WLC) group, children in the active treatment group (TX) would demonstrate significantly greater improvements on diagnostic status and a range of symptom measures, as well as a greater reduction in maladaptive cognitive biases including intolerance of uncertainty, negative beliefs about worry, cognitive avoidance, and negative problem orientation. It was further hypothesised that gains made by the TX group at post-treatment would be maintained or enhanced at 3-month follow-up.

Method

Participants

Participants were 42 children (14 males and 28 females), aged 7 to 12 years (M = 9.64, SD = 1.41) with a primary clinical diagnosis of GAD, and at least one of their parents. Seventy-one percent of children were born in Australia, with the remainder born in New Zealand (14.3%), the United Kingdom (11.9%) and South Africa (2.4%). None of the children identified as being of Aboriginal or Torres Strait Islander origin. The majority of children (73.8%) were living in families with both biological parents, and on average, children came from middle- to high-income Australian families as assessed through combined family income and parent education levels. Table 1 presents the sociodemographic information for participants.

Table 2 provides an overview of the diagnostic profile of all children included in this study. On average, children presented with 3.69 clinical diagnoses (SD=1.70). Overall, 9.5% of children presented with GAD only, 11.9% presented with two clinical diagnoses, 31% presented with three clinical diagnoses, 21.4% presented with four clinical diagnoses and the remaining 26.2% presented with five or more clinical diagnoses.

Insert Table 1 and 2 here.

Children were included in the study if they were aged between 7 and 12 years, had a minimum reading level of 7 years and met DSM-IV-TR criteria (APA, 2000) for a primary diagnosis of GAD according to the Anxiety Disorder Interview Schedule – Child Interview Schedule (ADIS-C/P; Silverman & Albano, 1996). As determined by the clinician administering the ADIS-C/P, the GAD diagnosis was required to have a clinical severity rating (CSR) of at least 4 (on a 0 to 8 scale) for inclusion in the study. Comorbidity with other anxiety disorders, depression, and externalising disorders was permissible, providing that GAD was considered to be the primary diagnosis (i.e., most severe and interfering). Children were not permitted to enter the study if they were

diagnosed with a pervasive developmental disorder, intellectual handicap or learning disability, or if they were found to have behavioural problems more impairing than anxiety, substance abuse, self-harm or suicidal ideation. Children were also excluded if they were currently receiving psychological assistance or medical treatment. Children excluded due to these criteria were provided with referrals to appropriate mental health services. All clinicians administering the ADIS-C/P were blind to both experimental condition and client history.

Figure 1 illustrates the flow of participants through the study. As can be seen in Figure 1, 42 families were allocated to either the treatment group (*n*=20) or the waitlist control group (*n*=22). Two treatment group families withdrew prior to Session 2; one due to illness and the other due to legal custody issues. One treatment client failed to complete diagnostic interviews at post-treatment (but completed post-treatment questionnaires as well as 3-month follow-up interviews and questionnaires). Two treatment clients failed to complete 3-month follow-up assessments. For the waitlist group, there were two dropouts prior to the end of the waiting period, with both families deciding to seek therapy elsewhere.

Measures

The primary (diagnostic status and severity) and secondary (child- and parent-report of worry/anxiety symptoms and cognitive variables associated with worry) outcome measures are described below.

Primary outcome measures

Diagnostic Status. Diagnostic status of children was assessed using the Anxiety Disorder Interview Schedule – Child Interview Schedule (ADIS-C/P; Silverman & Albano, 1996) with the same parent interviewed at each time point. The ADIS-C/P is a semi-structured interview developed specifically for the diagnosis of anxiety and other related disorders in children and adolescents, and is organised according to the diagnostic categories of the DSM-IV-TR (Silverman & Albano, 1996). The ADIS-C/P

includes a parent interview schedule (ADIS-P) and a child interview schedule (ADIS-C) and allows clinicians to establish a clinical severity rating (CSR) for each diagnosis ranging from 0 (*no interference with daily functioning*) to 8 (*extreme interference with daily life*) based upon child and parent report (Silverman & Albano, 1996). A CSR rating of 4 and above indicates the presence of a clinical-level disorder according to the DSM-IV-TR (APA, 2000), and only those children who received a primary diagnosis of GAD were included in this study. The ADIS-C/P and all outcome questionnaires (outlined below) were administered at pre-treatment and post-treatment for both the TX and WLC group, and at 3-month follow-up for TX participants only. The ADIS-C/P interviews were conducted either face-to-face or over the telephone, by provisionally registered Psychologists who were provided with a minimum of eight hours of training, and who were blind to both experimental condition and client history. Each interview was moderated by a supervising Clinical Psychologist and each interviewer received ongoing supervision for the interviews they conducted. At each time point a *combined* diagnostic profile was obtained, based on consensus meetings and review of both the parent and child report.

All ADIS interviews were recorded with the consent of participants. A random sample of 20% of these interviews was used to determine diagnostic reliability. Independent interviewers who were blind to the participant's original diagnoses, listened to and watched these recordings to derive their own diagnoses. Inter-reliability estimates were then calculated by comparing the original diagnoses and CSR ratings to those obtained by the independent interviewer. High inter-assessor reliability was found for both primary diagnosis and CSR rating, with a kappa value of 1 and a correlation of 0.96 respectively.

Clinician Rated Assessment of Functioning. Children’s overall level of functioning was assessed using the Children's Global Assessment Scale (CGAS; Shaffer et al., 1983). Values on the CGAS range from 1 to 100, where higher numbers are

indicative of higher levels of functioning (Shaffer et al., 1983). According to the CGAS, scores between 81 and 100 indicate a normal, healthy level of functioning; scores between 61 and 80 represent slight impairments; scores of 41 to 60 indicate a moderate degree of impairment in functioning; and scores between 1 and 40 indicate serious disability (Shaffer et al., 1983). In this study, scores on the CGAS were derived based on information obtained from the ADIS-C/P interviews and were rated by the same clinician administering the ADIS-C/P. The CGAS has been found to be a reliable and valid measure of overall functioning, with an inter-rater reliability estimate of 0.84 and a test-retest reliability over 6-months of 0.85 (Shaffer et al., 1983).

Secondary Outcome Measures

Parents and children completed a battery of online questionnaires designed to assess worry, GAD and its associated cognitive processes, and general anxiety symptoms.

Demographic Information. Parents provided information about themselves (including their name, age, gender, country of birth, occupation, income and living arrangements) and their child (including their name, age, gender, and country of birth).

Child Internalising Behaviours. Child internalising symptoms were assessed using the 32-item Internalising subscale of the Child Behaviour Checklist 6-18 (CBCL-Int; Achenbach & Rescorla, 2001). The CBCL-Int requires parents to indicate how often each symptom occurs on a 3-point Likert scale ranging from 0 (*Never*) to 2 (*Often*). Scores on the CBCL-Int may range from 0 to 64, with higher scores indicating greater internalising difficulties. Internal reliability estimates for the CBCL 6-18 have been found to range from 0.78 to 0.97 for the various subscales (Achenbach & Rescorla, 2001). The CBCL 6-18 also has excellent test -retest reliability over an eight day period (r = 0.82 - 0.94) (Achenbach & Rescorla, 2001).

Child Anxiety Symptoms – parent and child report. The Spence Children's Anxiety Scale (SCAS; Spence, 1998) and the Spence Child Anxiety Scale for Parents

(SCAS-P; Spence, 1999) were used to assess anxiety symptoms in children. The SCAS (44-items) and the SCAS-P (38-items) assess specific anxiety symptoms based on the DSM-IV-TR (APA, 2000). For each item of the SCAS/SCAS-P, participants are asked to indicate how often each symptom occurs on a 4-point Likert scale ranging from 0 (*Never*) to 3 (*Always*). A total score as well as six subscale scores (social anxiety disorder, separation anxiety disorder, panic attacks/agoraphobia, obsessive-compulsive disorder, generalised anxiety disorder and physical injury fears) can be derived. Only the SCAS/SCAS-P total score and the GAD subscale scores were used in this study. The total score may range from 0 to 114, with higher scores indicating greater anxiety symptoms. The GAD subscale score may range from 0 to 18, with higher scores indicating greater GAD symptoms. Research utilising the SCAS/SCAS-P has demonstrated acceptable internal consistency for the total score (Cronbach's alpha ranging between 0.89 and 0.92) and for the individual subscales (Cronbach's alpha ranging between 0.57 and 0.82) (Muris, Schmidt, & Merckelbach, 2000; Nauta et al., 2004; Spence, 1998; Spence, Barrett, & Turner, 2003).

Quality of Life. The Paediatric Quality of Life Inventory (QoL) was used to assess children's health-related quality of life according to the guidelines prescribed by the World Health Organisation (Varni, Seid, & Rode, 1999). The QoL contains 23 items and asks respondents to indicate how often they (or their child) experience each item on a 5-point Likert scale ranging from 0 (*Never*) to 4 (*Almost Always*). The QoL evaluates a child's functioning across four domains: physical; social; emotional; and school functioning. Child and parent reports were used in this study. Raw scores on the QoL are transformed into scaled scores out of 100, with higher scores being indicative of better quality of life (Varni et al., 1999). The psychometric properties of the QoL are satisfactory (Varni et al., 1999).

Child Worry. Child worry was assessed using the revised, 11-item Penn State Worry Questionnaire for Children (PSWQ-C; Chorpita, Tracey, Brown, Collica, &

Barlow, 1997). The PSWQ-C is an adaptation of the Penn State Worry Questionnaire (PSWQ; Chorpita et al., 1997), and assesses a child's general propensity to worry. Each item on the PSWQ-C requires children to indicate how true each statement is for them on a 4-point Likert scale ranging from 0 (*Not at all true*) to 3 (*Always true*). Scores may range from zero to 33, with higher scores indicating a greater tendency to worry. The PSWQ-C has been shown to yield a Cronbach's coefficient alpha of 0.89 for young children (Muris, Meesters, & Gobel, 2001).

Child Intolerance of Uncertainty. The 27-item Intolerance of Uncertainty Scale for Children (IUS-C) was used to assess children's intolerance of uncertainty and tendency to react negatively to uncertain situations and events on an emotional, cognitive and behavioural level (Comer et al., 2009). Each item on the IUS-C requires children to rate the degree to which they agree with each statement on a 5-point Likert scale ranging from 1 (*Not at all*) to 5 (*Very much*). Scores on the IUS-C may range from 27 to 135, with higher scores indicating greater intolerance of uncertainty. Comer et al., (2009) found excellent internal consistency for the IUS-C for both a community sample ($\alpha = 0.91$) and an anxiety-disordered sample ($\alpha = 0.94$) of youth aged 7 to 17 years.

Child Positive and Negative Beliefs about Worry. Child Positive and Negative Beliefs about Worry (PBW and NBW) were measured using the PBW and NBW subscales of the Meta-Cognitions Questionnaire for Children (MCQ-C; Bacow et al., 2009). The PBW and NBW subscales of the MCQ-C each contain six items and require children to indicate the degree to which they agree with each statement on a 4-point Likert scale ranging from 1 (*Do not agree*) to 4 (*Agree very much*). Scores on the PBW and NBW subscales may range from six to 24, with higher scores being indicative of greater PBW and NBW respectively. Cronbach's alphas have been found to range between 0.60 to 0.89 for the PBW subscale and between 0.74 to 0.76 for the NBW subscale (Bacow et al., 2009).

Child Negative Problem Orientation. Child Negative Problem Orientation (NPO) was measured using the 5-item subscale of the Social Problem Solving Revised Short-Form (SPSI-R-SF; D'Zurilla, Nezu, & Maydeu-Olivares, 2002). Each item asks children to rate how true each item is for them on a 5-point Likert scale ranging from 0 (*Not at all true of me*) to 4 (*Extremely true of me*). Scores on the NPO subscale of the SPSI-R-SF may range from zero to 20, with higher scores indicating a more negative problem orientation. Minor wording modifications were made to two items to suit a younger population. For example, "When I am faced with a difficult problem, I doubt that I will be able to solve it on my own no matter how hard I try" was modified to read "When I faced a difficult problem, I don't believe I can solve it no matter how hard I try". The NPO subscale has been shown to yield a Cronbach's alpha level of 0.83-0.86 and a test-retest reliability of 0.79 over a three week period in adults (D'Zurilla et al., 2002; Hawkins, Sofronoff, & Sheffield, 2009). To the author's knowledge, this measure is yet to be validated in children.

***Child Cognitive Avoidance*.** The 15-item White Bear Suppression Inventory (WBSI) was used to measure child cognitive avoidance (Wegner & Zanakos, 1994). The WBSI comprises statements to which children indicate their agreement on a 5-point Likert scale ranging from 1 (*Strongly disagree*) to 5 (*Strongly agree*). Scores on the WBSI may range from 15 to 75, with higher scores indicating greater cognitive avoidance. Minor wording modifications were made to three items to suit a younger population. For example, "There are images that come to mind that I cannot erase" was modified to read "There are pictures that come to mind that I cannot get rid of". Farrell and Barrett (2006) used a modified version of the WBSI with children aged 6 to 17 years, yielding comparable internal consistency estimates to the original WBSI (Cronbach's alpha of 0.93 for children and 0.91 for adolescents).

***Child Perfectionism*.** The Child and Adolescent Perfectionism Scale (CAPS) is a 22-item self-report questionnaire that was employed to assess two dimensions of

perfectionism: self-oriented perfectionism (SOP; the setting of demanding, stringent standards of performance or behaviour for oneself); and socially prescribed perfectionism (SPP; a desire to achieve unrealistic standards or expectations and to be perfect because of perceived or real pressure from significant others). The CAPS asks children to indicate how true each item is of them on a 5-point Likert scale ranging from 1 (*False – Not at all true of me)* to 5 (*Very true of me*). The CAPS total score, as well as the SOP and SPP subscale scores, were used in this study. The total score on the CAPS may range from 22 to 110, scores on the SOP subscale may range from 12 to 60, and scores on the SPP may range from 10 to 50, with higher scores indicating greater perfectionism. The CAPS has been shown to yield a Cronbach's alpha level of 0.85 and a test-retest reliability of 0.83 over a one week period (Castro et al., 2004).

Treatment satisfaction. Immediately following the end of treatment, satisfaction with the intervention was assessed through an 8-item, author-developed questionnaire. Parents and children rated on a 5-point Likert scale ranging from 0 (*Not at all)* to 4 (*Very much)* how satisfied they were with various aspects of the program. The mean item rating for parents and children was used to assess treatment satisfaction. Example items include "*How much did the No Worries! program help you to feel less anxious"* (child), and *"How much did the No Worries! program help to reduce your child's anxiety?"* (parent).

Procedure

Prior to commencement of the study, ethical approval was obtained from the Griffith University Human Research Ethics Committee and Brisbane Catholic Education. Participants were referred by parents, teachers, guidance officer networks, school newsletters, child and youth mental health services as well as through social media forums (i.e., Facebook). Following referral, all potential participants were screened using a 10 minute screening interview in order to assess for broad inclusion and exclusion criteria. This initial screening interview was conducted over the telephone

with the child's parent. If, from this interview, the child was assessed as potentially suitable for the study, the family was invited to complete the ADIS-C/P interviews and the online questionnaires. Both parent and child were required to provide their written consent to participate in this study.

Following diagnostic assessment and after the family had been deemed eligible to participate, the family was randomly allocated to either the treatment condition (TX) or the waitlist control (WLC) condition via a computer generated, blocked randomisation list. A block size of eight that was stratified according to treatment condition (TX or WLC) was used, and all families were informed of their condition by the primary researcher. After allocation, the TX group immediately commenced the treatment program and were reassessed at post-treatment and 3-month follow-up. In total, there were 7 treatment groups with 5 to 7 children in each group. After their 12 week wait, the WLC group were reassessed (i.e., diagnostic interviews and online questionnaires) and ceased to be part of the study, as it was deemed unethical to withhold treatment for longer than the post-treatment period. Immediately following their follow-up, all WLC participants were offered the treatment program. All treatment was conducted face-to-face, onsite at the Griffith University psychology clinics by provisionally registered Psychologists who were post-graduate students receiving advanced clinical training. All therapists were supervised weekly by registered Clinical Psychologists.

Content of the intervention

Based on theoretical and empirical research relating to the development and maintenance of excessive worry and GAD, the No Worries! program was developed to target intolerance of uncertainty (IU), negative beliefs about worry (NBW), negative problem orientation (NPO), and cognitive avoidance (CA) as well as symptoms commonly reported by children with GAD including sleep difficulties and perfectionism. The No Worries! program is a manualised, group-based, cognitively-

focussed treatment program and consists of 10 weekly sessions, each of 90 minutes duration, followed by two booster sessions, conducted one and three months after completion of the initial program. Parents concurrently complete seven sessions, each of 90 minutes duration, as well as two booster sessions. Three therapists are required to facilitate the No Worries! Program; two for the child sessions and one for the parent sessions.

Session-by-session outlines for the child and parent components of the No Worries! program are provided in Table 3. The anxiety management strategies covered in the No Worries! program include some generic CBT components such as psychoeducation about anxiety and worry, relaxation training (i.e., controlled breathing and progressive muscle relaxation) and the A-B-C model. However, the majority of the program is dedicated to targeting children's IU, NBW, NPO, CA, sleep issues associated with worry, and perfectionism. All sessions were videotaped with the consent of participants, and a random 20% of all group sessions were rated by an independent assessor to determine treatment fidelity. It was found that 97.63% of activities were completed according to the treatment manual.

Developing approaches to explain cognitive constructs such as IU, NBW, NPO and CA to children can be challenging and requires significant creativity. Worry and the cognitive processes associated with it are abstract and therefore difficult for young children to grasp. The challenge for a developmentally sensitive cognitive program is to transform abstract meta-cognitive processes into concrete, tangible examples for children, with the aim of educating them about worry "thought traps" and providing them with empowering approaches to manage and master their worry. The No Worries! Program therefore utilises narrative therapy approaches and frames pathological worry as a child's "Worry Beast", who is controlling and demanding of the children. For example their "worry beast" demands "You must be perfect – making mistakes is really bad". The goal of each session then, is to help children to understand the demands of

their worry beast (i.e., to be perfect, to need to know things absolutely for sure etc.), to explore how these demands impact on their lives and to teach children alternative strategies they can implement to tame their Worry Beast It should be noted that greater detail around the composition of the "No Worries!" program is documented in a paper that is currently under review (Holmes, Farrell, & Donovan, Unpublished).

Insert Table 3 here.

Results

Statistical Analyses

Efficacy of the intervention was evaluated using both completer and intent-to-treat (ITT) samples. The completer sample comprised those participants who had completed all the particular measures at the particular time points under consideration, while the ITT sample comprised all participants allocated to condition. As has been used by prominent researchers in the field, missing data was replaced using the last observation carried forward (LOCF) method for the ITT sample (March et al., 2009; McEvoy, Nathan, Rapee, & Campbell, 2012; Payne et al., 2011).

For both completer and ITT samples, in order to evaluate treatment effects from pre- to post-treatment, a series of chi-square analyses (for categorical variables) and 2 (Condition: TX, WLC) X 2 (Time: Pre, Post) mixed-factorial repeated measures ANOVAs (for continuous variables) were performed. For assessment of the 3-month follow-up data, only the TX group was available and the analytic method was different for completer and ITT samples. For the completer sample, because of various missing data at each time point, repeated measures ANOVAs were conducted from pre-assessment to 3-month follow-up, and then separately from post-assessment to 3-month follow-up, to ensure that as much data was retained as possible. For the ITT sample, repeated measures ANOVAs across the three time points were conducted. Where

significant time effects were found, simple contrasts were conducted to assess between which two time points the significant differences lay.

Indication of effect size was presented using partial eta-squared (η^2). According to Cohen (1988) for analyses conducted using repeated measures between groups ANOVAs, the guidelines for magnitude of η^2 are that .02, .13 and .26 indicate small, medium and large effect sizes respectively. For the repeated measures ANOVAs and simple contrasts conducted in the follow-up analyses, Cohen (1988) suggests that the guidelines for eta squared are followed whereby .01, .06, and .14 are indicative of small, medium and large effect sizes respectively

Pre-Treatment Comparisons

Preliminary analyses were conducted to ensure there were no pre-existing differences between the TX and WLC group on sociodemographic (age and gender), primary or secondary outcome variables at baseline. There were no significant differences between the groups on child age, $F(1, 40) = .001$, $\eta^2 < .001$, $p = .39$, gender, $\chi^2 (1, n = 42) = 0.56$, $p = .44$, or number of anxiety diagnoses, $F(1, 40) = .57$, $\eta^2 = .01$, $p = .45$. Similarly, there were no significant multivariate group differences for the CSR or CGAS, Pillai's $F(2,39) = .36$, $p = .70$, $\eta^2 = .02$, the parent-rated questionnaires, Pillai's $F(4,37) = 1.01$, $p = .41$, $\eta^2 = .10$ or the child self-report questionnaires, Pillai's $F(7,34) = 1.26$, $p = .29$, $\eta^2 = .21$.

Satisfaction with treatment and session attendance

As discussed above, satisfaction with treatment was computed using the mean item rating for both parents and children. A rating of 2 indicates '*a little bit'* satisfied, 3 indicates '*quite a bit*' satisfied and a rating of 4 indicates '*a lot*' satisfied. The results suggest that satisfaction with the treatment program was moderate for both children ($M = 2.88$, $SD = 0.67$) and parents ($M = 3.27$, $SD = 0.61$). On average, children in the treatment group attended 9.39 treatment sessions ($SD = 0.92$), and 1.61 booster sessions ($SD = 0.61$).

Completer Analyses: Pre- to Post-Treatment

Tables 4 and 5 outline the means (*M*), standard deviations (*SD*) and Cronbach's Alpha (α) for each of the primary and secondary outcome variables for pre-treatment, post-treatment, and 3-month follow-up for the completer sample. Table 6 outlines the results of the repeated measures ANOVAs conducted for each of the primary and secondary outcome variables from pre-treatment to 3-month follow-up for the completer sample. For ease of interpretation, treatment results have been presented separately for primary and secondary outcome measures.

Insert Tables 4, 5 and 6 here

Primary Outcome Measures. At post-treatment, significantly more children in the TX condition compared to children in the WLC condition were free of their GAD diagnosis, χ^2 (1, *n*=36) = 13.41, *p* = .000. Specifically, at the post-assessment time-point, 52.9% of children in the TX condition and 0% of children in the WLC condition were free of their GAD diagnosis. Additionally, 17.6% of children in the TX condition no longer met criteria for any diagnosis, compared to 0% of children in the WLC condition. This difference between the TX condition and the WLC condition approached significance, χ^2 (1, *n* = 36) = 3.66, *p* = .056.

Furthermore, compared to children in the WLC group, children in the TX group demonstrated a greater reduction in the number of anxiety diagnoses, and clinical severity (CSR) of their GAD diagnosis, as well as a greater increase in their overall functioning (CGAS) from pre- to post-treatment. Furthermore, at post-assessment, the CSR of the TX group had fallen within the non-clinical range (*M*=3.59, *SD*=1.33), while the CSR for the WLC group had not (*M*=6.21, *SD*=0.79). There was a significant group effect on the CSR (F (1, 34) = 25.69, *p*= <.001, η^2 = .43) and CGAS (F (1, 34) = 6.06, *p*= .02, η^2 = .15).

Secondary outcome measures – child-rated. With respect to child-rated secondary outcome measures, compared to children in the WLC group, children in the

TX group demonstrated a greater reduction in worry symptoms, and a greater improvement in overall quality of life from pre- to post-treatment. However, children in both groups reported equal improvement from pre- to post-treatment on measures of IU, NPO, NBW, CA, total perfectionism, SOP, and SPP. No improvements were observed for either group on the SCAS-TOTAL, SCAS-GAD or PBW questionnaires. There were no significant group effects for any of the secondary outcome measures.

Secondary outcome measures – parent-rated. With respect to parent-rated secondary outcome measures, it is evident from Table 6 that parents of children in both the TX and WLC group reported equal improvement in their child's internalising behaviour, anxiety symptoms and overall quality of life from pre- to post-treatment. It is noteworthy, that the group by time interaction for the SCAS-P-GAD approached significance (p = .053).

Completer Analyses: 3-month Follow-up

Primary Outcome Measures. As is evident from Table 4, at 3-month follow-up, 100% of children no longer met diagnostic criteria for GAD. Furthermore, the percentage of children who were free of *any* diagnosis had risen from 17.6% at post-treatment, to 50% at 3-month follow-up. It is noteworthy that, for those children who still met criteria for a diagnosis at 3-month follow-up, social phobia was the most common remaining anxiety diagnosis (n=4), followed by specific phobias (n=3), and oppositional defiant disorder (n=1). Furthermore, as is evident from Table 4, improvements made by the TX group from pre- to post-treatment on number of anxiety diagnoses, GAD severity, and overall level of functioning were further enhanced at 3-month follow-up.

Secondary outcome measures – child-rated. Improvements made by children in the TX group from pre- to post-treatment on *worry* and overall *quality of life* were enhanced further by 3-month follow-up. With respect to the results for IU, CA, NBW, NPO, total perfectionism, SOP and SPP, given that both the TX and WLC groups

improved equally from pre- to post-treatment on these measures, improvements evident at 3-month follow-up may represent maintenance or further improvement due to treatment, or may simply be due to the passage of time. Given improvements from pre- to post-treatment on the SCAS-Total and SCAS-GAD were not evident for either the TX or WLC groups, improvements demonstrated by the TX group at 3-month follow-up suggest that treatment effects may have taken longer to emerge on these measures. Again, there were no significant effects for PBW.

Secondary outcome measures – parent-rated. As is evident in Table 6, significant improvements were observed from pre-treatment to 3-month follow-up and from post-treatment to 3-month follow-up for the SCAS-P-Total, the SCAS-P-GAD, the CBCL-Int, and QoL. However, given that the TX and WLC groups improved equally on these measures from pre- to post-treatment, it is difficult to determine whether the improvements seen from post-treatment to 3-month follow-up for the TX group on these measures represented further improvements due to treatment or were simply due to the passage of time.

Intent-to-treat Sample (ITT)

For the ITT sample, significantly more children in the TX condition compared to the WLC condition were free of their GAD diagnosis, χ^2 (1, n = 42) = 12.60, p = .000, with 45% of children in the TX group and 0% of the WLC group being free of their GAD diagnosis at post-treatment. Additionally, 15% of children in the TX condition no longer met criteria for any diagnosis, compared to 0% in the WLC condition. This difference between the TX condition and the WLC condition approached significance, χ^2 (1, n = 42) = 3.55, p = .059. By 3-month follow-up, 88.88% of children were free of their GAD diagnosis, and 44.44% of children were free of all diagnoses.

As there was relatively little missing data, it is not surprising to find that the results of the ITT analyses closely mirror those using the completer sample. There were no differences in the interpretation of results between completer and ITT analyses with

respect to primary outcome measures, or the child self-report questionnaires. For parent-rated secondary outcome measures, one difference between the completer and ITT samples was found on the SCAS-P-GAD. For the ITT sample, a significant time effect, $F(1,40) = 11.47$, $p = .002$, $\eta^2 = .22$, *and* a significant group by time effect, $F(1,40) = 4.15$, $p = .048$, $\eta^2 = .09$ were found on the SCAS-P-GAD, suggesting that parents of children in the TX group reported greater improvements in their child's GAD symptoms compared to parents of WLC group children. At 3-month follow-up, there were no differences in the interpretation of results between the completer and ITT samples with respect to primary outcome measures, child-rated questionnaires or parent-rated questionnaires.

Subsidiary Analyses: Responders versus Non-Responders

Supplementary analyses examined whether there were any pre-treatment differences between children who responded to the program (i.e., no longer met diagnostic criteria for their primary diagnosis of GAD following treatment) versus those who did not respond to the program at post-assessment (i.e., retained their primary diagnosis of GAD). A series of between groups ANOVAs were conducted on age, gender and primary and secondary outcome measures. For post-treatment response, children who no longer met criteria for their primary diagnosis of GAD were not found to differ from children who retained their primary diagnosis of GAD on any demographic, primary or secondary outcome measures (either parent- or child-rated). Given that 100% of children in the TX group no longer met criteria for their primary diagnosis of GAD by 3-month follow-up, it was not possible to conduct the same analyses at 3-months.

Supplementary analyses also examined whether there were any pre-treatment differences between children who no longer met diagnostic criteria for all clinical diagnoses, versus children who did not. A series of between groups ANOVAs were conducted on all pre-treatment demographic variables (i.e., age, gender and SES) and

primary and secondary outcome measures. For post-treatment response, results were only significant for the CSR, F(1,34) =14.15, p = .001, η^2 = .294, and CGAS, F(1,34) = 9.27, p = .004, η^2 = .214, such that compared to those who retained some sort of anxiety diagnosis at post-treatment, those who no longer met diagnostic criteria for any diagnosis at post-assessment, had a lower pre-treatment GAD CSR and a higher overall level of functioning at pre-treatment. For 3-month follow-up treatment response, results were significant for the CGAS, F(1,14) = 4.95, p = .04, η^2 = .261, number of pre-treatment diagnoses, F(1,14) = 7.98, p = .014, η^2 = .363, and cognitive avoidance, F(1,14) = 5.53, p = 5.53, η^2 = .283, such that compared to those children who retained some sort of clinical diagnosis at 3-month follow-up, those children who did not had a higher overall level of functioning prior to treatment, fewer clinical diagnoses at pre-treatment and reported lower levels of cognitive avoidance at pre-treatment.

Discussion

This study sought to investigate the efficacy of a disorder-specific treatment program for childhood GAD. It was hypothesised that compared to children in the waitlist control (WLC) group, children who had undergone treatment (TX) would demonstrate greater improvements on diagnostic status, symptoms and quality of life. Further, it was hypothesised that children in the TX condition would report greater reductions in the cognitive biases of intolerance of uncertainty, negative beliefs about worry, negative problem orientation and cognitive avoidance. It was further hypothesised that improvements would be maintained or enhanced at 3-month follow-up.

The results for the primary outcome measures largely supported the hypotheses. At post-treatment, significantly more children in the TX group compared to children in the WLC group no longer met diagnostic criteria for GAD. However, the groups were not found to differ from pre- to post-treatment with respect to the loss of all clinical diagnoses, although this difference approached significance. By 3-month follow-up, all

children no longer met diagnostic criteria for GAD, and half the sample was completely diagnosis free. Children in the TX group also evidenced a greater reduction in the severity of their GAD diagnosis and number of anxiety diagnoses, as well as a significantly greater increase in their overall functioning, compared to children in the WLC group.

Comparing the results of this study with those of earlier ones is difficult given that all five previous studies investigating children with GAD specifically, were a) case series rather than RCTs, and b) involved treatment that was conducted in an individual rather than group format. However, reflecting back on those studies, it would seem that the post-assessment results of the present study for loss of primary GAD diagnosis were somewhat lower than those reported by Eisen and Silverman (1993, 1998) who provided children with a transdiagnostic anxiety program. In their earlier trial, three of the four children no longer met diagnostic criteria for GAD, whilst all children no longer met diagnostic criteria for GAD at post-treatment in the latter trial. The results of the current study are comparable, if not superior to those of Eisen and Silverman (1993, 1998) however, when looking at treatment response at 3-month follow-up for the present study, where 100% of children were free of their GAD diagnosis.

In terms of GAD-specific interventions for children, the only comparable study (as it was the only one that involved children under the age of 12 years) was that conducted by Payne et al., (2011) who found that at post-treatment 81% of children and adolescents no longer met diagnostic criteria for GAD and 59% no longer met diagnostic criteria for any comorbid diagnosis. Again, at post-treatment, the remission rates produced in the current study were somewhat lower than those produced by Payne et al., (2011), but were superior by 3-month follow-up. Thus, it would seem that overall, the disorder-specific program tested in this study was effective in treating children with GAD and that although moderate improvements were seen at post-treatment, by 3-month follow-up GAD was ameliorated in every case. The enhanced effect at 3-month

follow-up is interesting. Given that GAD is a complex, largely cognitive disorder, it might be the case that following Session 10, and in the lead up to their 3-month follow-up assessment, children had more 'real life' opportunities to implement, and consequently consolidate, the treatment strategies taught. The two booster sessions between Session 10 and the 3-month follow-up may have further contributed to the enhanced effect at the 3-month assessment point

As noted above, although all children no longer met diagnostic criteria for GAD at 3-month follow-up, 50% of children retained a diagnosis of either social phobia or specific phobia. The finding that social phobia remained as a diagnosis in some children (but not all) is not surprising given that social phobia (particularly in children) is considered notoriously resistant to treatment regardless of whether the treatment is specific to social phobia or transdiagnostic in nature (Kendall, Settipani, & Cummings, 2012). Given that exposure is considered to be the most important CBT treatment component in the treatment of phobias (including social phobia), and that most disorder-specific and transdiagnostic programs for social phobia and specific phobia include exposure, it might be useful to develop and evaluate an additional optional treatment module focusing on exposure for children who retain these residual diagnoses following treatment. Similarly, most treatment programs for social phobia include social skills training (SST). It may therefore be useful to develop and evaluate an additional optional treatment module for children with residual social anxiety that focuses on teaching the child practical skills to interact and engage with others.

The results with respect to pre-treatment differences between those children who recovered (i.e., no longer met criteria for any clinical diagnosis) and those who did not were not surprising. Those children who recovered at post-treatment had less severe pre-treatment GAD and higher overall quality of life compared to children who did not lose all clinical diagnoses at post-treatment. Similarly, children who had recovered by 3-month follow-up were more likely to have less severe pre-treatment GAD, fewer

clinical diagnoses, and lower levels of cognitive avoidance. It is logical that children who are less severe and better functioning are more likely to lose their diagnoses as there are fewer clinical symptoms to treat and therefore fewer improvements to be made. Furthermore, children would be able to more easily direct their acquired skills to more simple and contained contexts. The finding that children who recovered at 3-months had lower pre-treatment levels of cognitive avoidance is interesting, and also seems logical from a theoretical perspective. In their seminal work, Wegner and Zanakos (1994) highlight a number of problems associated with suppressing one's thoughts. First, the more someone attempts not to think about a particular thought, the more likely they are to think about it. Second, whilst a thought is supposedly suppressed in the short term, it is likely to be enhanced in the long term, a phenomenon known as the "Rebound Effect" (Wegner & Zanakos, 1994). Thus, children who employ less cognitive avoidance are more likely to respond better to treatment, as they consciously process, rather than actively avoid, unpleasant worry thoughts. By not avoiding their thoughts, children are also more likely to deal with their worry thoughts in a timely fashion. Therefore, those children who endorse elevated levels of cognitive avoidance at pre-treatment may require additional assistance when it comes to learning adaptive skills for coping with unpleasant mental thoughts/images. It is noteworthy that the analyses conducted with respect to treatment response were somewhat underpowered and hence should be interpreted with caution. Studies with larger sample sizes would enable researchers to better assess predictors of treatment outcome.

In terms of the questionnaire data, there were several important findings. Compared to children in the WLC group, children in the TX group demonstrated greater improvements from pre- to post-treatment on child-rated levels of excessive worry, and child-rated quality of life, and these gains were enhanced further by 3-month follow-up. For all other parent- and child-rated secondary outcome measures (with the exception of PBW), children in the TX and WLC groups either improved to the same degree or there

were no differences evident at post-treatment. At 3-month follow-up however, children in the TX group evidenced significant improvements with respect to these cognitive variables. Given that the program used in this study was almost entirely cognitive in nature, it might be the case that treatment effects take longer to emerge, as cognitive shifts may take a little longer to occur. Alternatively, it is also possible that children may not have understood the questions being asked of them in these questionnaires. Future research may consider modifying/reviewing the self-report questionnaires to be more child-friendly, or may experiment with changing the mode of delivery of these questionnaires to enhance understanding (e.g., reading questions aloud to children). However, although it seems likely that the improvements were due to the treatment itself, we cannot unequivocally state this with any certainty due to the lack of a WLC group at 3-month follow-up and the alternative explanation that improvements were simply due to the passage of time. Although inclusion of a waitlist group at 3-month would have strengthened the study, there are significant ethical implications for withholding treatment for extended periods of time, especially given the nature and severity of the children included in this study.

Finally, the null results pertaining to PBW are consistent with recent research suggesting that NBW may be more related to worry than PBW in young children (Bacow et al., 2010; Bacow et al., 2009; Holmes, Donovan, Farrell, et al., Under Review; Holmes, Donovan, & Farrell, Under Review). Indeed, in this study, PBW was the only cognitive variable for which neither time effect nor group by time effects were found in any of the analyses. Given that researchers have found that adults and adolescents (as young as 14 years) endorse PBW and that these beliefs are implicated in the worry process, it might be that PBW represent higher-order cognitive processes that emerge once children reach a certain level of cognitive maturity (Dugas et al., 1998; Dugas, Marchand, & Ladouceur, 2005; Laugesen et al., 2003). Determination of the age

at which PBW emerge as an important predictor of worry will be an important and interesting area of empirical enquiry.

Strengths, limitations and suggestions for future research.

This study had several strengths. To the best of the author's knowledge, it was the first randomised controlled trial (RCT) investigating the efficacy of a disorder-specific treatment program for children aged 7 to 12 years with a primary diagnosis of GAD that targeted the cognitive variables suggested to be important in the development and maintenance of the disorder. This study also employed multiple informants in the data collection phase (including clinicians, parents and children). In particular, all children were diagnosed according to the ADIS-C/P, which meant that treatment effects were not solely based on self- and parent-report (Silverman & Albano, 1996). This study progresses the field by using a rigorous design, and incorporates measurement of the cognitive biases being targeted in treatment. Furthermore, this study includes follow-up to three months to assess durability of gains and consolidation of treatment effects. Another strength of the current study was the use of group CBT treatment rather than traditional individual therapy, which is potentially a cost-effective way to deliver therapy to a large population of clinically anxious children. Furthermore, given that research investigating the cognitive components of child worry is in its infancy, another strength of the current study was the inclusion of cognitive measures developed for use with children. Finally, all clinical interviewers were blind to both experimental condition and client history, thus ensuring that the interviews were valid, unbiased assessments of the child's current functioning.

Despite its strengths however, this study was not without its limitations. First, although only a pilot study in nature, the current investigation would have benefited from a larger sample size and less attrition. Second, the results of this research might be limited in terms of generalizability due to the demographics of the sample. The sample was of high socioeconomic status and parental education level, and was comprised of

mothers predominately from Australia. Future research should endeavour to gain a more ethnically diverse sample comprising a combination of mothers and fathers with varying socio-economic backgrounds and education levels. Finally, the present study would have benefited from longer term follow-up assessment points. Future research should aim to replicate the results of this study with additional follow-ups at 6- and 12-months to establish the long-term durability of the program.

In addition to the suggestions for future research discussed above, there are a number of other avenues worthy of further investigation. It would be worthwhile comparing the program tested in this study to a transdiagnostic CBT program to determine whether the outcomes achieved for children with GAD are in fact better than what would be achieved with traditional child anxiety treatment programs that do not target the cognitive processes known to be associated with GAD. It would be also interesting to investigate whether transdiagnostic CBT programs are able to alter children's intolerance of uncertainty, negative beliefs about worry, negative problem orientation, and cognitive avoidance without formally targeting them. Another important area for future empirical enquiry is to investigate moderators and mediators of change in this population, so as to better understand the mechanisms by which this program produced change. In particular, investigations regarding the possible moderating effect of age may be important. Despite significant attempts to ensure that the program was developmentally appropriate, it may be that younger children struggled more with some of the content and/or had more difficulty concentrating than older children. Alternatively, there may be different mechanisms of change for younger versus older children. Future research should attempt to recruit sufficient sample sizes to examine potential moderators and mechanisms of change in disorder-specific programs.

The results of this study are novel and exciting, and suggest that a disorder-specific treatment program targeting the cognitive variables thought to underpin GAD,

is beneficial for young children suffering from this debilitating disorder. Further, the cognitive program was well accepted by families, with moderate to high satisfaction ratings and positive written feedback. It is hoped that the results of this study, and future others that will extend and improve upon it, will go some way towards alleviating the suffering and disability experienced by children and their families as a result of this disorder.

Registration

This Randomised Controlled Trial is registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR); Registration Number: ACTRN12612000061831, http://www.anzctr.org.au/ .

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Conflict of Interest

None declared.

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Table 1.

Sociodemographic details for the total sample, separated by group membership.

	TX Group (n = 20)	WLC Group (n = 22)	Total Sample (n = 42)
Gender (%)			
Male	25	40.9	33.3
Female	75	59.1	66.7
Age in Years (SD)			
Child	9.65 (1.66)	9.64 (1.18)	9.64 (1.41)
Parent (Mother)	41.45 (5.27)	42.14 (3.75)	41.81 (4.50)
Child's Country of Birth (%)			
Australia	80	68.2	71.4
United Kingdom	10	13.6	11.9
New Zealand	10	13.6	14.3
South Africa	0	4.5	2.4
Living Arrangements (%)			
Mother/Father	80	68.2	73.8
Mother	15	31.8	23.8
Mother/Step-Father	5	0	2.4
Combined family income (%)			
<$20,000	0	0	0
$21,000 - $40,000	0	9.1	0
$41,000 - $60,000	0	0	2.4
$61,000 - $80,000	10	13.6	9.5
$81,000 - $100,000	25	31.8	33.3
>$100,000	65	45.5	54.8
Highest level of education (%)			
Mother			

Completed Year 10	15	9.1	11.9
Completed Year 12	20	22.7	21.4
TAFE / Apprenticeship	25	31.8	28.6
Undergraduate University Degree	20	22.7	21.4
Postgraduate University Degree	20	13.6	16.7
Father			
Completed Year 10	15	22.7	11.9
Completed Year 12	20	13.6	14.3
TAFE / Apprenticeship	25	31.8	33.3
Undergraduate University Degree	20	18.2	19.0
Postgraduate University Degree	20	9.1	19
Unknown	0	4.5	2.4

Note. SD = Standard Deviation.

Table 2.

Diagnostic Profile of Children in the study.

	Diagnosis Number						
	Second	Third	Fourth	Fifth	Sixth	Seventh	Eighth
Separation Anxiety Disorder	14	9	4	0	0	0	0
Specific Phobia – Total	5	9	8	9	3	2	1
Social Phobia	15	12	4	1	0	0	0
Dysthymia	1	1	0	0	1	0	0
Major Depressive Disorder	1	0	0	0	0	1	0
ADHD	2	1	2	1	3	0	0
ODD	1	2	2	0	1	0	0
None	3	8	22	31	34	39	41

Note: All children held a primary diagnosis of GAD. ADHD = Attention Deficit Hyperactivity Disorder; ODD = Oppositional Defiant Disorder.

Table 3.

Session by session description of the No Worries! program – Child and Parent Program.

Session	Children	Parents
1	• Introduction, normalisation of anxiety and worry • Rationale for treatment and explanation of key terms • Goal setting and homework	• Introduction, normalisation of anxiety and worry • Rationale treatment • Psychoeducation – child anxiety, worry and GAD • Overview of cognitive model of GAD • Goal setting and homework
2	• Quiz • Thoughts, feelings and behaviours • Homework	• Thoughts, feelings, behaviours • Body signs and relaxation and troubleshooting • Homework
3	• Quiz • Body signs and relaxation • Homework	• Psychoeducation and strategies on parenting an anxious child • Development of a new parenting plan • Homework
4	• *Joint Session with Parents* • Quiz • Sleep hygiene • Development of a new sleep routine • Homework	
5	• Quiz • Dealing with uncertainty and	• Review of theoretical model of GAD from Session 1

	reassurance seeking • Homework	• Dealing with uncertainty and reassurance seeking • Understanding the power of thoughts through imaginal activities (White Bear Experiment) • Thought suppression and negative beliefs about worry
6	• Quiz • Understanding the power of thoughts through imaginal activities (White Bear Experiment) • Thought suppression and negative beliefs about worry • Homework	• Probability overestimation and coping underestimation • Problem solving and problem orientation • Homework
7	• Quiz • Probability overestimation and coping underestimation • Homework	• Perfectionism • Informal review of program content • Troubleshooting future difficulties
8	• Quiz • Problem solving and problem orientation • Homework	
9	• Quiz • Perfectionism • Homework	
10	• Quiz	

- Review of program content through game

Table 4

Values for primary outcome measures for the completer sample from pre-treatment to 3-month follow-up.

	Pre-Treatment		Post-Treatment		3-month Follow-Up
	Tx Group	WLC Group	Tx Group	WLC Group	Tx Group
Free of Primary Diagnosis					
N	0	0	9	0	16
%	0%	0%	52.9%*	0%	100%
Free of Any Diagnosis					
N	0	0	3	0	8
%	0%	0%	17.6%	0%	50%
Number of Diagnoses					
M	3.82	3.74	2.06*	3.37	0.75#
(SD)	1.60	1.88	1.48	1.77	(0.93)
Clinician Severity Rating (CSR)					
M	6.00	6.26	3.59*	6.21	2.25#
(SD)	(1.28)	(0.73)	(1.33)	(0.79)	(0.68)
Children's Global Assessment of Functioning (CGAS)					
M	50.71	50.16	63.82*	51.05	75.44#
(SD)	(8.91)	(7.06)	(11.03)	(7.66)	5.82

Note. Tx = Treatment group; WLC = Waitlist Control Group; SD = Standard Deviation; CSR = Clinician Severity Ratings - these range from 0 (low) to 8 (high); CGAS = Children's Global Assessment Scale - these range from 0 (poorest level of functioning) to 100 (highest level of functioning); * = a significant difference between TX group and WLC group at post-treatment; # = a significant difference for TX group from post-treatment to 3-month follow-up

Table 5

Means and SDs for all Child Secondary Outcome Measures Across Occasions and Conditions (completer sample)

Measure	Pre-Treatment		Post-Treatment		3-month Follow-Up
	Tx Group	WLC Group	Tx Group	WLC Group	Tx Group
Quality of Life (QoL) – Child Report (α = 0.90)					
M	67.87	69.96	76.09	66.88	80.84#
(SD)	(13.82)	(8.14)	(15.17)	(12.03)	(13.28)
Quality of Life (QoL) – Parent Report (α = 0.78)					
M	67.87	69.97	79.17	75.34	84.78#
(SD)	(13.82)	(8.14)	(14.16)	(11.74)	(11.08)
Spence Children's Anxiety Scale – Total Score (SCAS-P-TOTAL) (α = 0.90)					
M	41.22	35.90	29.94	31.47	21.81#
(SD)	(14.75)	(13.41)	(12.70)	(8.79)	(12.76)
Spence Children's Anxiety Scale – GAD Subscale Score (SCAS-P-GAD) (α = 0.75)					
M	8.67	7.47	6.17	6.84	4.69#
(SD)	(3.12)	(3.08)	(2.71)	(2.29)	(3.28)
Child Behaviour Checklist – Internalising Subscale – T-Scores (CBCL-INT) (α = 0.95)					
M	72.28	67.58	64.44	62.95	57.25#
(SD)	(11.04)	(7.16)	(10.43)	(7.34)	(8.23)
Child Worry (α = 0.86)					
M	20.39	20.21	13.00	17.90	9.81#
(SD)	(5.66)	(7.33)	(6.70)	(7.02)	(5.44)
Spence Children's Anxiety Scale – Total Score (SCAS-Total) (α = 0.90)					
M	40.29	35.90	34.88	40.84	22.56#
(SD)	(14.65)	(13.41)	(20.25)	(19.93)	(13.57)

Spence Children's Anxiety Scale – GAD Subscale Score (SCAS-GAD) (α = 0.78)					
M	8.47	7.47	7.41	8.42	4.75#
(SD)	(3.11)	(3.08)	(4.65)	(4.56)	(2.89)
Child Intolerance of Uncertainty (IU) (α = 0.95)					
M	78.83	81.32	58.83	73.05	50.56
(SD)	(23.23)	(27.15)	(20.29)	(21.43)	(18.22)
Child Negative Problem Orientation (NPO) (α = 0.82)					
M	11.61	12.37	6.89	9.90	7.19
(SD)	(4.41)	(5.53)	(4.21)	(5.45)	(4.39)
Child Positive Beliefs about Worry (PBW) (α = 0.78)					
M	9.28	9.11	8.28	8.84	7.63
(SD)	(3.30)	(4.29)	(1.87)	(4.41)	(2.19)
Child Negative Beliefs about Worry (NBW) (α = 0.76)					
M	16.22	17.79	13.00	15.95	12.13
(SD)	(3.49)	(4.65)	(4.59)	(4.65)	(3.85)
Child Cognitive Avoidance (CA) (α = 0.85)					
M	56.94	57.05	48.06	54.53	40.50
(SD)	(6.09)	(12.53)	(13.52)	(12.82)	(15.11)
Child Perfectionism Total Score (Total Perfectionism) (α = 0.90)					
M	61.65	61.53	50.82	56.47	46.88
(SD)	(13.20)	(18.36)	(14.73)	(15.13)	(15.18)
Child Self-Oriented Perfectionism (SOP) (α = 0.89)					
M	40.82	38.05	32.82	34.90	30.94
(SD)	(10.71)	(11.07)	(11.06)	(9.41)	(10.78)
Child Socially Prescribed Perfectionism (SPP) (α = 0.85)					
M	20.82	23.47	18.00	21.58	15.94

(SD)	(6.12)	(9.51)	(5.94)	(8.00)	(6.62)

Note. Tx = Treatment group; WLC = Waitlist Control Group; SD = Standard Deviation; α = Cronbach's Alpha; * = a significant difference between TX group and WLC group at post-treatment; # = a significant difference for TX group from post-treatment to 3-month follow-up.

Table 6.

Results of Repeated Measures ANOVAs for the Completer Sample from Pre-Treatment to 3-month Follow-Up.

	Pre- to Post-Treatment						Pre-treatment to 3-month follow-up			Post-treatment to 3-month follow-up		
	Time Effects			Group x Time Effects			Time Effects			Time Effects		
	F	*p*	η^2	*F*	*p*	η^2	*F*	*p*	η^2	*F*	*p*	η^2
Primary Outcome Measures												
Number of Anxiety Diagnoses	47.09	.000	.58	20.17	.000	.37	125.95	.000	.90	17.80	.001	.56
CSR	36.28	.000	.52	33.25	.000	.49	211.40	.000	.93	32.89	.000	.70
CGAS	42.43	.000	.55	32.29	.000	.49	260.21	.000	.95	30.11	.000	.68
Secondary Outcome Measures – Child Rated												
Worry	20.75	.000	.37	32.29	.023	.14	21.80	.000	.59	9.62	.007	.39
IU	11.14	.002	.24	1.92	.174	.05	12.61	003	.46	11.07	.005	.43
NBW	11.66	.002	.25	.866	.358	.02	9.92	.007	.40	2.66	.124	.15
PBW	1.58	.218	.04	.536	.469	.02	2.18	.160	.13	3.85	.069	.20
NPO	18.86	.000	.35	1.84	.183	.05	14.10	.002	.49	.084	.776	.01
CA	9.14	.005	.21	2.84	.101	.08	13.30	.002	.47	15.72	.001	.51
Total perfectionism	10.36	.003	.23	1.37	.250	.04	19.67	.000	.57	3.39	.085	.18
SOP	9.76	.004	.22	1.84	.184	.05	17.67	.001	.54	1.77	.203	.11
SPP	5.34	.027	.14	.207	.652	.01	13.84	.002	.48	2.69	.122	.15
SCAS-C-TOTAL	.004	.950	.000	2.02	.164	.06	11.28	.004	.43	5.95	.028	.28
SCAS-C-GAD	.005	.946	.000	1.52	.227	.04	11.57	.004	.44	5.00	.041	.25
QoL	1.08	.307	.030	5.23	.028	.13	9.05	.009	.38	9.09	.009	.38
Secondary Outcome Measures – Parent Rated												
SCAS-P-TOTAL	12.71	.001	.27	2.42	.128	.13	22.78	.000	.60	20.25	.000	.57
SCAS-P-GAD	11.29	.002	.24	4.02	.053	.10	26.27	.000	.64	10.13	.006	.40
CBCL-Int	18.49	.000	.35	1.22	.277	.03	18.40	.001	.55	11.64	.004	.44
QoL	14.51	.001	.29	1.83	.185	.05	23.44	.000	.61	7.28	.017	.33

Note. CSR = Clinician Severity Rating; CGAS = Children's Global Assessment of Functioning; IU = Intolerance of Uncertainty; NBW = Negative Beliefs about Worry; PBW = Positive Beliefs about Worry; NPO = Negative Problem Orientation; CA = Cognitive Avoidance; SOP = Self Oriented Perfectionism; SPP = Socially Prescribed Perfectionism; SCAS-C-TOTAL = Spence Children's Anxiety Scale – Total Score, Child Report; SCAS-C-GAD = Spence Children's Anxiety Scale – GAD Score, Child Report; QoL = Quality of Life; SCAS-P-TOTAL = Spence Children's Anxiety Scale – Total Score, Parent Report; SCAS-P-GAD = Spence Children's Anxiety Scale – GAD Score, Parent Report.

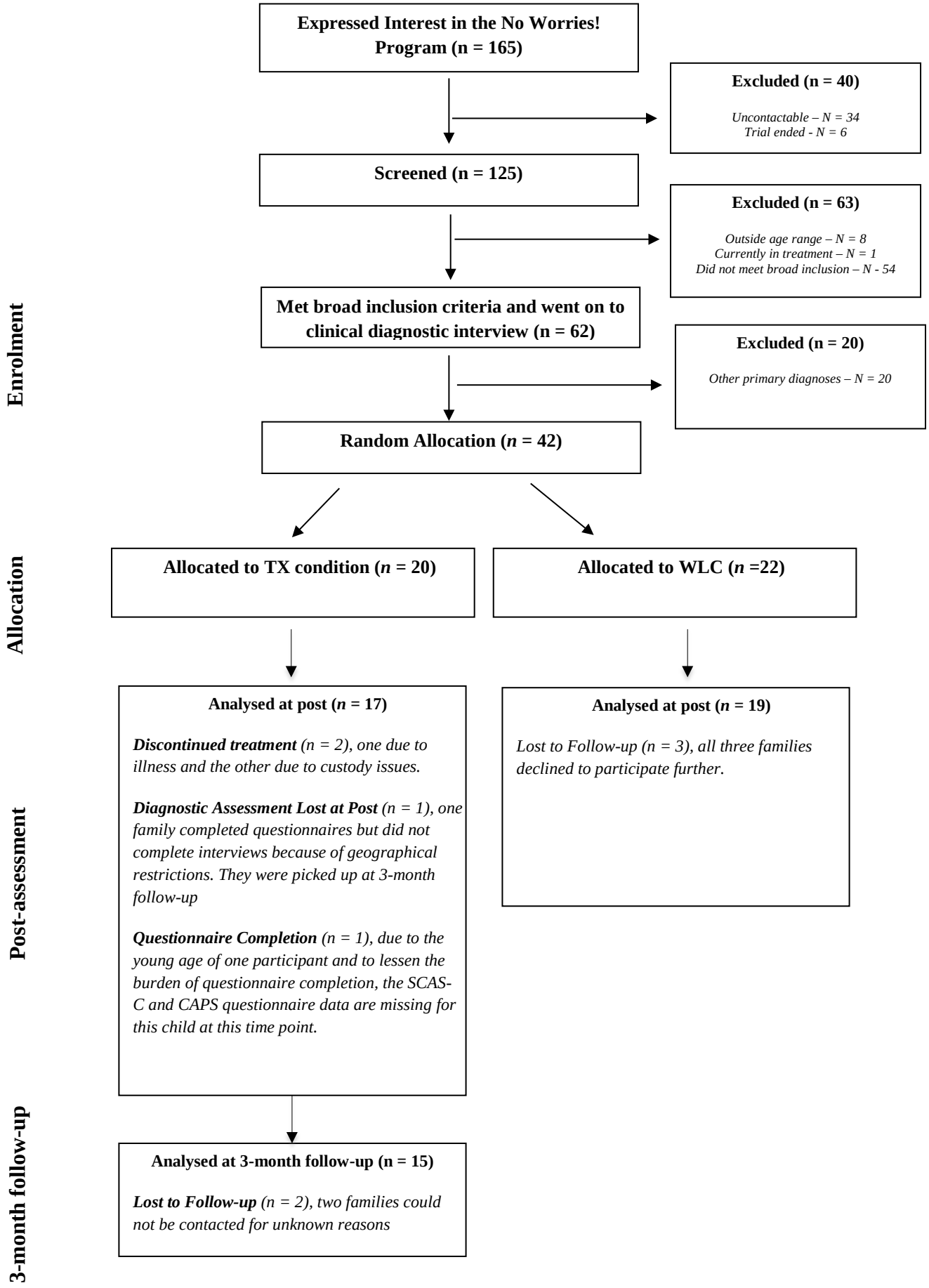

Figure 1. Flow diagram of participants' progress through phases of the study.