Cover page

A randomized-controlled trial of therapy for children and adolescents with anxiety disorders and OCD

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1. Project Title:

A randomized-controlled trial of therapy for children and adolescents with anxiety disorders and OCD

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3. Abstract:

Anxiety disorders are among the most common psychiatric disorders in children and typically produce significant disruption in family, social, and academic functioning (Kathleen Rise Merikangas & Avenevoli, 2002). Fortunately, cognitive behavioral therapy (CBT) for childhood anxiety has been manualized and found to be efficacious (Walkup et al., 2008). CBT most often incorporate aspects of cognitive-restructuring, relaxation training, and exposure to anxiety-producing stimuli. Although research suggests that exposure is the most effective treatment component (S. P. H. Whiteside et al., 2020), many practitioners opt to utilize mainly cognitive and relaxation techniques at the expense of exposure techniques (S. P. H. Whiteside, B. J. Deacon, K. Benito, & E. Stewart, 2016). Parent-coached exposure therapy (PCET) is a treatment designed to maximize efficacy by highlighting exposure and has preliminary support (S. P. H. Whiteside et al., 2015). The current study aims to provide a more definitive test of the efficacy of PCET through a larger randomized controlled trial. In addition, the study will examine the effectiveness of individual as well as intensive group PCET. Finally, exploratory analyses will examine the effect of delivering treatment via video visits versus in person therapy. Sixty children and adolescents seeking treatment for anxiety in an outpatient pediatric anxiety clinic will be randomized to receive either individual PCET, individual traditional CBT, or the 5day intensive group PCET. The representativeness of the sample will be examined through a chart review of data collected in a clinical database (IRB# 611-05) of patients that accept and those that decline participation in the treatment study. Data regarding symptoms and impairment will be gathered from child- and parent-report, as well as clinical evaluators at the initial consultation,

immediately before beginning treatment, at mid-treatment, and post-treatment. Patients in the individual therapy condition will be allowed to access visits in person or via video. We anticipate that children treated with PCET will demonstrate significantly greater improvement and require fewer total treatment sessions, than those in traditional CBT. Support of this hypothesis would clarify the active ingredients in manualized treatment for childhood anxiety disorders and would potentially lead to quicker, more efficient treatment.

4. Background and Significance:

Childhood anxiety disorders (CADs; including obsessive compulsive disorder which is commonly comorbid and addressed with the same behavioral treatment strategies) are one of the most common mental health problems, affecting an estimated 2.8 to 31.9% of youth worldwide (Cartwright-Hatton, McNicol, & Doubleday, 2006; Costello, Egger, & Angold, 2005; Erskine et al., 2017; Kathleen Ries Merikangas et al., 2010). Furthermore, CADs are associated with significant impairment across several domains (e.g., social, health, academic/professional, etc.) both during childhood and later in life (de Lijster et al., 2018; Mychailyszyn, Méndez, & Kendall, 2010; Nail et al., 2015; Strauss, Frame, & Forehand, 1987). Cognitive-behavioral therapy (CBT) holds the most empirical support for the treatment of CADs and has been found to be effective (Chorpita et al., 2011; Kendall, 1994; Kendall et al., 1997; Pliszka & AACAP, 2007; Reynolds, Wilson, Austin, & Hooper, 2012; Wang et al., 2017), though it largely underperforms other exposure-based treatments (Ale, McCarthy, Rothschild, & Whiteside, 2015). The dominant presentation of CBT for CADs incorporates a combination of sessions dedicated to anxiety management strategies (AMS; e.g., emotion identification, relaxation training, worry re-scripting, etc.) followed by exposure-focused sessions (Kendall, 1994; Kendall et al., 1997). Unfortunately, the addition of AMS lays in opposition to inhibitory learning theory and may unintentionally delay and dilute exposure (Hembree & Brinen, 2009), potentially reducing treatment effectiveness (Craske et al., 2008; Craske et al., 2006; Craske, Treanor, Conway, Zbozinek, & Vervliet, 2014; S. P. Whiteside et al., 2015; S. P. Whiteside, L. A. Sim, et al., 2020).

Despite longstanding recognition of exposure as the active ingredient in such treatments (Ale et al., 2015; Barlow, 2004; S. P. Whiteside, L. A. Sim, et al., 2020), access to this intervention remains limited (Costello et al., 2005; S. P. Whiteside, B. J. Deacon, K. Benito, & E. Stewart, 2016), leaving inumerable children's and adolescents' symptoms undertreated. Clinician hesitation to provide exposure therapy for CADs may be partially attributable to misconceptions that exposure would be ineffective for and intolerable by children, that the therapeutic relationship could be damaged by difficult exposures, and that parents would react negatively to the introduction of exposure-related methods (Crawley et al., 2013; Deacon et al., 2013; Kendall et al., 1997; Manassis, Russell, & Newton, 2010; Reid et al., 2017). Such concerns have likely contributed to the popularity of methodologies that combine exposure with AMS. However, research has indicated that children actually tolerate exposure very well and that exposure-focused treatment can be highly effective in the amelioration of CADs (S. P. Whiteside et al., 2015; Stephen P Whiteside et al., under review; Stephen P. Whiteside, Ollendick, & Biggs, 2020). This supports the need for professionals who provide and study exposure therapy to make it more accessible to both practitioners and families alike.

Accordingly, efforts to maximize the effectiveness, efficiency, and accessibility of CBT for CADs have been implemented within a pediatric anxiety specialty clinic, resulting in the

formulation of parent-coached exposure therapy (PCET). Aspects of PCET have been described previously in both an individual and group format (S. P. Whiteside, J. E. Dammann, M. S. Tiede, B. K. Biggs, & A. Hillson Jensen, 2018; Stephen P Whiteside & Jacobsen, 2010; Stephen P Whiteside et al., 2014). To date the empirical support for PCET consists of a pilot feasibility study of the individual format (S. P. H. Whiteside et al., 2015), a baseline-controlled study of the individual-based 5day intensive for OCD (S. P. Whiteside et al., 2014), and an uncontrolled clinical examination of the group-based 5day intensive for anxiety and OCD (S. P. H. Whiteside, J. E. Dammann, M. S. Tiede, B. K. Biggs, & A. Hillson Jensen, 2018). The study is designed to provide a more definitive examination of the efficacy of PCET.

5. Specific Aim:

The specific aims in the current study are as follows:

1. *Examine the effectiveness of PCET through baseline comparisons*. All families in the Pediatric Anxiety Disorders Clinic (PADC) complete clinical assessments during the initial evaluation. All families eligible for anxiety treatment within the PADC will be invited to complete research assessments immediately prior to treatment, mid-treatment, and post treatment. This data will be used for a baseline-controlled evaluation of treatment effectiveness, i.e. symptoms change from clinical assessment to pre-assessment will be compared with change from pre-treatment to post-treatment.

2. *Comparative effectiveness of individual PCET and individual standard CBT*. The relative effectiveness of individual PCET and standard CBT will be examined through symptom change from pre-treatment to mid-treatment and post-treatment.

3. *Comparative efficiency of individual PCET and individual standard CBT*. The relative efficiency of individual PCET and standard CBT will be examined through the total number of sessions that patients attend over the 14 weeks of the study.

4. *Comparative effectiveness of group intensive PCET, individual PCET, and individual standard CBT*. The relative effectiveness of group intensive PCET versus individual PCET and standard CBT will be examined through symptom change from pre-treatment to mid-treatment and post-treatment.

5. *Acceptability*. The acceptability of the treatments will be examined through parent and child ratings of therapist alliance and satisfaction with services.

6. Research Plan:

Recruitment. The Pediatric Anxiety Disorder Clinic (PADC) receives referrals and provides treatment services to children with anxiety disorders. Families who come to the PADC for outpatient services will receive a verbal description of the clinical trial at their initial appointment. This description will be provided by the clinician conducting their evaluation.

Participants. A total of 120 families (240 participants) (40 in each treatment condition) children and adolescents (aged 7 – 18 years) along with their parents will participate in the current study. The PADC typically evaluates more than 350 patients per year, approximately one-third of which continue into the treatment program. Thus, we anticipate a recruitment period of approximately twelve months in order to reach our goal of enrolling 240 participants in the study. To determine the degree to which the current study sample reflects the population of patients seen in the PADC, the clinical assessment data will be compared to patients not enrolled in the study, but for whom Research Authorization is available.

To be included, participants must a) be age 7 to 17, or 18 if still in high school and living at home; b) have a DSM-5 anxiety disorder diagnosis, including generalized anxiety disorder, obsessive compulsive disorder, panic disorder, agoraphobia, separation anxiety disorder, social and specific phobias, as assessed on the relevant modules of the (MINI-Kids; (Sheehan et al., 2010) by study staff in the PADC, c) be appropriate for the PADC standard weekly outpatient therapy program, d) be interested in starting outpatient therapy, e) have the anxiety disorder as their primary diagnosis, f) if taking a selective serotonin reuptake inhibitor, SNRI, tricyclic, or antipsychotic medication, agree to no changes during the 14 weeks of the study (medication status will be recorded from interview and using review of the electronic medical record).

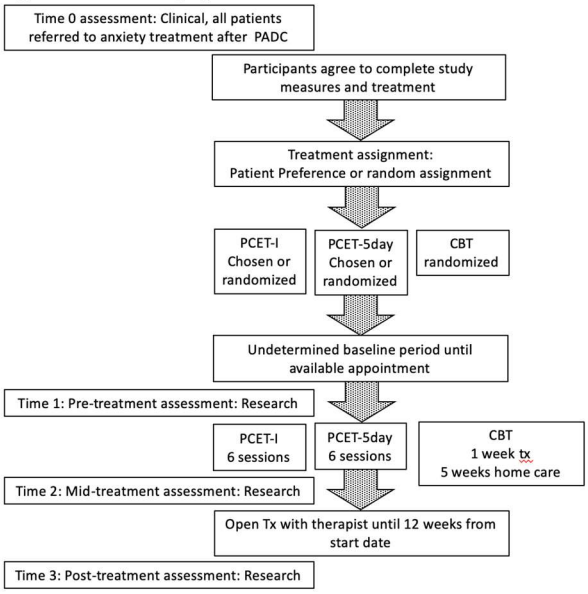
Patients will be excluded from the study if they meet any of the following criteria: (a) history of and/or current psychosis, autism, bipolar disorder, or current suicidality, or eating disorder as assessed during the initial clinical interview and all available clinical information; (b) current positive diagnosis in the child's caregiver of mental retardation, psychosis, or other psychiatric disorders or conditions that would limit his/her ability to understand CBT and follow-through with treatment directives (based on clinical interview); (c) secondary diagnosis of oppositional defiant disorder or major depression of sufficient severity to prevent anxiety treatment, (d) severity of symptoms that warrant higher level of care (i.e. intensive, residential, IOP, inpatient), (e) family is unable to attend weekly sessions (i.e. geographical or scheduling barriers), of (f) history of good quality exposure or CBT.

Procedures

See Figure 1. Participants who have contacted or been referred to the PADC for evaluation and treatment of an anxiety disorder will complete the standard clinical intake procedure for the PADC. Families whose children meet the inclusion criteria will be provided a description of the study procedures and asked which aspects of the study they are willing to participate in. All families will be asked to complete three research assessments (pre-, mid-, and post-treatment) consisting of completing questionnaires and a short phone or video call. Families will be provided with a description of the three treatment options and informed that PCET is the default treatment option. They will then be asked if they are willing to be randomized to a treatment from two or three of the options. Randomization will be accomplished through a random number generator and will allow for a comparison of the relative effectiveness of each treatment by

controlling for other variables that might impact treatment outcome. The individual PCET is currently the standard treatment offered through the PADC and patients not interested in this treatment are not eligible for the study. When families are interested and eligible in participating in the clinical trial, the therapist or a study coordinator will obtain written consent and assent. Families who decline to participate will have the option of participating in treatment as usual in the PADC.

Figure 1. Study procedure



Following the consent process, families who agreed to be randomized to a comparison treatment participate will be assigned to a treatment condition through random assignment. Families that did not agree to randomization will be scheduled in PCET (individual or intensive group depending on preference). The families will then be scheduled to begin therapy at the earliest date available. All enrolled families will complete the pre-treatment research assessment the day they begin treatment. The families will then begin treatment.

The mid-treatment evaluation will be completed after the sixth session for patients in the individual treatment conditions and six weeks after the start of treatment in the intensive group condition. After the mid-treatment assessment families in all conditions can receive any type of therapy interventions with their study therapist. The final assessment will be completed 14 weeks after the first session. All study assessments and individual treatment sessions will be recorded, unless participants opt-out of recording, to examine therapist fidelity. Families will record progress each week using a study form which will be gathered by therapists during visits and by therapists (or other study staff) via electronic message or telephone calls in the absence of in-person appointments.

Tests/Measures Administered

Table 2 Summarizes when study measures are completed, by whom and whether they are administered as part of clinical practice or as part of the research study.

Interviewer--administered measures: The interviewer measures will be administered by the practicing clinician at initial clinical interviewer and by study staff blind to the treatment condition at pre-, mid-, and post-tx.

(1) The MINI-Kids (Sheehan et al., 2010). This is a clinician-administered, structured interview that is currently administered as part of the PADC standard evaluation. Administered at clinical interview only.

(2) Pediatric Anxiety Rating Scale *(PARS; (Group, 2002)*. The PARS is an interviewer administered scale consisting of five items assessing anxiety severity, frequency, distress, avoidance, and interference. The PARS has good psychometric properties (Group, 2002) and has been used as the primary continuous outcome measure in previous treatment studies (e.g., (Walkup et al., 2008).

(3) Clinical Global Impression Scale *(CGI;* (Guy, 1976; Health, 1985). The CGI includes: a) a global clinician rating of severity of psychopathology (GCI-S) ranging from 1 (*not at all ill)* to 7 (*extremely ill)*, with a score of 1 or 2 reflecting no to minimal symptoms (Health, 1985); and b) a global clinician rating of clinical improvement (CGI-I; (Guy, 1976). ranging from 1 ("very much improved) and 7 ("very much worse"). Consistent with previous studies (Ginsburg, et al., 2011), youths receiving a score of 1 ("very much improved") or 2 ("much improved") were considered treatment responders.

Parent- and child report measures:
(1) Demographic Form. This form will assess basic demographic information of the child like age, gender, treatment history, ethnicity/race, and family composition. Completed by parent only one time at clinical.

(2) Treatment Confidence. Parents can children will respond to eight questions assessing their confidence to manage anxiety symptoms and belief that in the effectiveness of different techniques to handle anxiety.

(3) Spence Children's Anxiety Scale-Child and Parent Versions (SCAS-C/P; (Spence, 1998). The SCAS-C/P are Likert-type self- and parent-report questionnaires designed to measure anxiety in children and adolescents. The SCAS-C/P yield a total score with six subscales, but only the total subscale was included in the current study as a measure of overall anxiety symptoms. Reliability and validity data are robust (Muris, Merckelbach, Ollendick, King, & Bogie, 2002; Muris, Schmidt, & Merckelbach, 2000; Spence, 1998).

(4) Child Sheehan Disability Scale for Children-Child and Parent Versions (CSDS-C/P(S. P. Whiteside, 2009) This scale allows the parent and child to rate the degree of impairment the child's symptom cause in social, schooling, and family domains, as well as allowing parents to rate the effect their child's symptoms has on the parent's work and social life. Administered at all four time points.

(5) Child Avoidance Measure Child and Parent Version (CAM-C/P) allows rating the degree to which the child avoid anxiety provoking stimuli. Administered at all four time points.

(6) Progress Monitoring Form. The parent and child will complete a weekly progress monitoring form in which they rate the severity of the child's symptoms from 0 to 10 and record implementation of homework and skills learned in therapy.

(7) Therapist Alliance Scale – Child/Parent (TAS-P; (TAS-C; assesses parent and child affect toward the therapist in seven items for parents (Shirk & Saiz, 1992) and 12 for child (Shirk & Saiz, 1992). Administered at post-tx only.

(8) Client Satisfaction Questionnaire-8 (CSQ-8; (Attkisson & Zwick, 1982). Parent satisfaction with services will be assessed at post-tx only.

Table 2.

	Time 0 **Clinical**	Time 1: Pre-Tx **Research**	Time 2: Mid-Tx (or week/session 6) **Research**	Time 1: Post-Tx (week 14) **Research**
Interviewer	MINI-Kids PARS CGI-S	PARS CGI-S/I	PARS CGI-S/I	PARS CGI-S/I
Parent	Demographic Form Treatment Confidence SCAS-P CSDS-P CAM-P	Treatment Confidence SCAS-P CSDS-P CAM-P	Treatment Confidence SCAS-P CSDS-P CAM-P	Treatment Confidence SCAS-P CSDS-P CAM-P TAS-P CSQ-8
Child	Treatment Confidence SCAS-C CSDS-C CAM-C	Treatment Confidence SCAS-C CSDS-C CAM-C	Treatment Confidence SCAS-C CSDS-C CAM-C	Treatment Confidence SCAS-C CSDS-C CAM-C TAS-C

Treatment

All treatments will be administered according to a written protocol. The amount of treatment contact (sessions, session hours, phone contacts, electronic messaging) will be tracked for analysis of efficiency.

Parent Coached Exposure Therapy-Individual (PCET-I). Patients and a parent in the PCET condition will begin by working with a therapist to create an individualized fear hierarchy consisting of the situations and stimuli that produce anxiety for the child, gradually progressing from less anxiety to more anxiety. Psychoeducation about the nature of anxiety, habituation, and the rationale for engaging in exposure therapy will also be provided in the first session. Over the

next five sessions, each patient and a parent will work with the therapist to engage in exposure sessions – the intentional prolonged exposure to a feared stimulus. The initial sessions will focus on anxiety-producing situations, activities, and stimuli that are lower on the child's hierarchy. With coaching from the therapist, the child will engage in each exposure session until new learning has been achieved. In this manner, the child will progress through the steps of his or her fear hierarchy. Parents will be involved in all sessions to learn to serve as "exposure coaches" for their child. Between each weekly session, the child will be given a homework assignment to complete exposures with the help of his or her parents. The therapists will use the Anxiety Coach website to deliver psychoeducation. In this condition patients will receive 6 one-hour sessions between pre-treatment and mid-treatment and an unlimited number of individual sessions (probably 2 based on pilot studies) between mid-treatment and post-treatment.

Traditional Cognitive Behavior Therapy (CBT). During this treatment arm, the therapist will review the anxiety management strategies presented in the first half of the Coping Cat treatment as used in the CAMS study (Compton et al., 2010). The procedures are presented in a logical order, but the therapist has the flexibility to alter treatment to the needs of the patient. However, during the 6-sessions in this treatment arm the therapist will not discuss exposure exercises. During the first session the therapist and child will participate in activities to get to know each other and participants will be introduced to the general concepts in cognitive-behavioral therapy, including the "CBT Triangle" comprised of thoughts, feelings, and behaviors. In the second session, participants will be coached in identifying and labeling anxiety; they will receive psychoeducation about physiological and autonomic responses to stress and anxiety. In the third session, participants will learn techniques for relaxation, including progressive muscle relaxation, guided imagery, and diaphragmatic breathing techniques. In the fourth session, participants will be introduced to cognitive restructuring techniques and will learn to identify "worry" thoughts and challenge them with "coping" thoughts. In the fifth session, participants will learn problem-solving techniques aimed at increasing cognitive flexibility in anxiety-producing situations. In the sixth session, participants and will be introduced to behavioral management techniques that involve rewarding positive coping behavior. Between each session, children will receive a homework assignment designed to facilitate their learning and applying each skill on their own. Treatment sessions in this arm include only the child minimal participation of a parent. After session 6, the therapist will administer exposure consistent with the PCET condition. In this condition patients will receive 6 one-hour individual sessions between pre-treatment and mid-treatment and an unlimited number of sessions (probably 3 based on pilot studies) between mid-treatment and post-treatment.

Parent Coached Exposure Therapy-5day Intensive (PCET-5day). Patients and a parent in the PCET-5day condition will receive treatment consistent with the PCET-I condition. However, the treatment will be delivered during nine appointments over five days in a group setting of 4 to 8 families. Consistent with clinical practice, during the five weeks following the intensive week the families will be expected to continue exposure therapy on their own with phone support as

needed. In-person appointments will be scheduled as needed based on symptom severity, patient need, or other factors if questions cannot be addressed or resolved via telephone. Following six weeks after the beginning of treatment, the families may have individual sessions as needed. In this condition patients will receive nine 1.5-hour group sessions and unlimited phone contact (probably 1 based on pilot studies) between pre-treatment and mid-treatment and an unlimited number of sessions (probably 0 based on pilot studies) between mid-treatment and post-treatment.

Treatment Integrity.
The integrity of treatment will be addressed as follows. All therapists will be trained in how to administer the treatment and will follow written session-by session treatment guidelines. Clinical Child Psychologist Bridget Biggs, Ph.D. who has been trained in the Coping Cat by recognized experts John Piacentini, Ph.D. at UCLA and faculty of the University of Kansas will train therapists in the Coping Cat. Dr. Whiteside will train therapists in PCET. After each session, therapists will record in writing the therapy components administered during the session. Study therapists will also participate in a weekly supervision meeting. All sessions will be audio recorded and coded to assess adherence to the treatment protocol, unless the family opts out.

Design Justification

The design of the current study is intended to maximize participation through providing options for participation. First, families have the option to provide data without submitting to randomization of treatment condition. The inclusion of families that are willing to complete the research assessments even though they are unwilling to be randomized to a comparison condition is intended to minimize the number of families that decline to participate. As such, this option increases the likelihood that participants accurately represent the population of patients seen in the PADC. Because these patients will receive PCET, it increases the number of patients receiving the intervention of most interest. In addition, because these families will participate in a baseline period of no treatment before attending the first treatment session, symptom improvement with treatment can be compared to that without treatment. Similarly, by allowing families to select the chance to be randomized to one or both CBT or PCET-5day as a comparator, we intend to maximize the number of patients for whom there is an acceptable option.

Personnel

Therapy will be provided by the staff of the PADC and psychology fellows that have completed the PADC rotation. The PI has trained and supervised all therapists and will provide additional training in the traditional CBT protocol. Assessments will be conducted by the study staff, blind to condition. The PI will provide training in the assessments.

Statistical Plan

We anticipate that all patients will see minimal improvement in symptoms during the baseline period between the clinical evaluation and baseline pre-tx, and significant improvement from pret-tx to mid-tx and post-tx. In addition, we hypothesize that patients treated in the either PCET condition will demonstrate greater reductions in anxiety symptoms and impairment, as well as require fewer total treatment sessions, compared to patients in traditional CBT. To test this hypothesis, repeated-measures analyses of variance (which controls for baseline symptom severity) will be conducted to assess the change that occurs over time and between conditions. Because treatment changes after mid-treatment for some conditions, but not others, we will examine the changes at mid-treatment and post-treatment separately. The primary outcome variable will be change in symptom severity on a continuous variable as measured by the IE administered CGI-S. Secondary outcomes will be anxiety symptoms measured through parent-report (SCAS-P), child-report (SCAS-C), and clinician report (PARS). Dichotomous measures of improvement used in the literature will include receiving a score of 1 or 2 on the CGI-I, reduction on the PARS of 35% (response) and 50% (remission). Tertiary outcome variables will be impairment measured through the CSDS. Efficiency will be measured at the group level by number of treatment hours (included phone contacts) and symptom change effect size per hour of intervention. Number of dropouts vs. completers will be examined. Finally, we will examine treatment acceptability through the rate of drop-out and ratings of alliance. All statistical analyses will be conducted using intent-to-treat and completer analyses. Because patients that agree to each randomization option may differ in unmeasured ways, comparator analyses will be run in two ways. First, to avoid biasing the results by combining incompatible groups, we will include patients in comparisons only if they agreed to be randomized to each option (i.e., only patients that agreed to the possibility of being randomized to CBT will be included in the comparison between PCET-I and CBT). Second, to maximize power, we include all patients with randomization agreement as between subject variables. Exploratory analyses will include examining the relation to randomization choices and the moderating effects on outcome of diagnosis (OCD vs. anxiety disorder), symptom severity, age, medication use, etc.

Power Statement: Based on the mean mid-tx CGI-S scores from the pilot study (PCET= 2.33, sd= .8; CBT = 3.17, sd =.8) and 14 patients are required per group to achieve 80% power to detect a difference between two groups at a *p* value of .05. Thus, the current proposed sample size of 20 participants be treatment conditions should be sufficient.

In regard to acceptability, we will assess the acceptability of each treatment to patients and their families. A between-groups analysis of variance will be conducted to assess for differences in the alliance and satisfaction of each treatment at posttreatment. Further, we will also conduct between-group mean comparisons of the number of drop outs.

Sample representativeness will be examined through group differences between patients that participated and those that declined through t-tests and chi-square analyses of symptom and demographic data collected at the clinical assessment.

Remuneration

Patients can earn up to $50 for participation: up to $25 for completing research assessments ($5 for pre-treatment assessment and $10 for each of the mid- and post-treatment assessments); up to $25 for randomization: $15 if they agree to the possibility of being randomized to one comparator and additional $10 for agreeing to be randomized to the second comparator. All remuneration will be paid when the participant completes the study, and may be pro-rated based on completion of assessments. Patient remuneration will be payed from Dr. Whiteside's research funds.

7. Possible Discomforts and Risks:

The risks associated with participation in the current pilot study generally do not rise above those associated with seeking treatment in an outpatient, academic hospital setting. Participants may experience mild discomfort associated with answering questions about themselves and discussing potentially difficult topics. However, most people welcome the opportunity to discuss their experiences with a trained clinician, and these activities are consistent with treatment guidelines and practices in an outpatient setting. As participants begin exposure exercises, they may experience increased distress and anxiety. This should be short-lived as they begin to habituate to their anxiety. Further, each subsequent exposure session should produce progressively less anxiety. It is important to note that engaging in exposure therapy is part of standard practice in the PADC and would be implemented as an integral component of each child's treatment for anxiety regardless of his or her participation in the current study.

Patient Safety. Patients in all aspects of the study at all times will have the same access to emergent care for symptoms in need of immediate evaluation and care, including but not limited to self-harm, suicidal ideation, or unsafe environments. First, throughout the duration of the study, patients will be enrolled in therapy and have a therapist available as they would outside of the study. Second, study participants will have access to the same after-hours emergency services (on-call physician, emergency department) as patients outside the study. Third, assessments done for study purposes (pre-treatment, mid-treatment, post-treatment) include an interview with study staff who will communicate any concerns to the patient's therapists and can also direct the patient to emergency services if needed. Fourth, study questionnaires do not inquire about high risk symptoms (i.e., suicidal thoughts or symptoms of depression) nor have free-response questions eliciting such information, so it is unlikely that such information would be conveyed undetected. Fourth, the study populations of children and adolescents with anxiety do not pose a high risk of self-harm, suicidal ideation, or unsafe environments, and those that do have such symptoms will be excluded from the study as their treatment needs are incompatible with the study treatment protocols.

8. Potential Benefits:

Participants may experience reductions in symptoms of anxiety and related distress by participating in treatment. They may also increase their knowledge of the nature of anxiety and expand their capacity for effectively coping with anxious distress. For patients that consent to randomization, we will attempt to schedule the first six appointments at the beginning to ensure treatment is delivered within the study timeline.

9. Conflict of Interest:

There is no conflict of interest involved with the study beyond the professional benefits from academic publication or presentation of the results.

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