OFFICIAL TITLE OF STUDY: A Single-Session Intervention for Families on Waitlists for Child Anxiety Treatment

NCT NUMBER: NCT05841680

DATE: 10-15-2025

PROTOCOL

Youth with Anxiety Disorders on Waitlists for Treatment: A Critical Need

Anxiety disorders are among the most prevalent and impairing disorders in children and adolescents ("youth") (CDC, 2022). It is well documented that the mental health system is under-resourced and unable to meet the treatment needs of youth, including youth with anxiety disorders, creating a bottleneck problem for service providers (Kazdin, 2019). This bottleneck results in lengthy wait lists for services, spanning months and even years in some instances (Blech et al., 2017; Stallard et al., 2007; Steinert et al., 2017). These lengthy wait times prolong the distress and impairment experienced by youth with anxiety disorders and their families.

These data highlight the critical need to move beyond traditional services delivery approaches for youth with anxiety disorders. In making this move, there is urgency to develop and evaluate least restrictive interventions that are both accessible to families and do not place further burden on the already under-resourced mental health system. As a step towards addressing this need, we propose to develop and evaluate a least restrictive intervention for families on waitlists for treatment of youth anxiety.

Single-Session Interventions Delivered Remotely: A Promising Solution

Digital and telehealth methods offer promising approaches for developing least restrictive interventions because they reduce burden and increase accessibility (Comer & Myers, 2016). We build on our prior work and leverage both of these methods, digital and telehealth, in developing a remotely-delivered single session intervention (SSI) for families on waitlists for anxiety services. SSIs condense and deliver evidence-based interventions within a single session; their brevity opens new avenues to increase access to and efficiency of care, and decrease length and cost of care (Schleider & Weisz, 2017; Schleider, 2020). Emerging evidence supports the promise of SSIs as stand-alone treatments and adjunctive treatments (Hoyt et al., 2018), including for anxiety disorders in youth (Schleider & Weisz, 2017). Further, data support the acceptability of SSIs to clients on waitlists for psychological services (Schleider et al., 2020b). However, we are not aware of any SSIs that have been developed and evaluated for youth on waitlists for anxiety treatment.

Our own data also support the promise of digital and telehealth methods and SSIs as least restrictive approaches to treating youth anxiety. This includes randomized controlled trial data supporting the efficacy of digitally-delivered attention training (e.g., Pettit et al., 2020, 2022) and promising pilot data supporting the feasibility and acceptability of a telehealth-delivered single session psychoeducation intervention for youth who experienced a return of anxiety following positive response to cognitive-behavioral treatment (Cabrera et al., 2022). In this proposal, we build on these supportive data and extend our efforts to a novel impacted population, families on waitlists for treatment of youth anxiety.

Anxiety Management Support While Families Wait: A Novel SSI

Our primary goal in developing a SSI for families on waitlists for treatment of youth anxiety is to provide short-term reductions in anxiety symptom severity and impairment while families wait for more intensive treatment. A secondary goal is to explore whether a SSI could reduce families' need for more intensive treatment, meaning that families no longer feel the need to pursue more intensive treatment following completion of the SSI. We ground our proposed SSI in cognitive behavioral principles because cognitive behavioral treatments (CBTs) are the leading evidence-based approach for anxiety disorders in youth (Higa-McMillan et al., 2016).

Because it is not feasible to include all components of CBTs for youth anxiety in a SSI, we prioritize evidence-based components that are able to be understood and implemented by families following only a single session. This includes psychoeducation on the cognitive behavioral conceptualization of anxiety, introduction to self-regulation strategies to manage physiological manifestations of anxiety, and cognitive restructuring of anxiogenic thoughts. Given parents' important roles in facilitating implementation and practice of material presented in CBT approaches for youth anxiety (Silverman & Kurtines, 1996), we also will involve parents in the SSI and present strategies on how parents can support their children in managing anxious feelings and thoughts. In designing the module, we will leverage best practices for remotely delivered SSIs, including the use of engaging visual content with corresponding audio and interactive vignettes as well as comprehension checks (Schleider et al., 2020a). Details on the SSI components are provided in Methods.

Specific Aims

We will pursue the following aims in N = 60 families on waitlists for outpatient psychosocial treatment for youth anxiety.

Aim 1 Pilot Phase: Develop and pilot a SSI tailored for families on waitlists for outpatient psychosocial treatment for youth anxiety disorders. We will pilot the SSI with N = 5 families and use cognitive response interviewing to obtain data from parents and children, ensuring the content is understandable and accessible. We will refine the SSI based on these data.

Following the Pilot Phase, we will enroll an additional N = 60 families and randomize them to either the SSI (n = 30) or waitlist control (n = 30)

Aim 2 Test Phase Acceptability, and Satisfaction: Examine acceptability of the refined SSI, as well as satisfaction with the SSI. We hypothesize that users will find the module to be acceptable and will report high satisfaction.

Aim 3 Test Phase Anxiety Outcomes: Demonstrate reductions in youth anxiety symptom severity. We hypothesize that anxiety symptom severity and impairment will be significantly lower among youth who receive the refined SSI relative to youth on waitlist control.

Approach

We will first pilot the SSI with five families and use cognitive response interviewing to obtain data from youth and parents, ensuring that the content is understandable and accessible. The SSI will be refined based on these data. Will then will evaluate the refined SSI in a sample of 60 youth participants and their parents. Participants recruited for this study will be youth 7-17 years old on waitlists at outpatient clinics to receive psychosocial treatment for anxiety disorders. Following an intake evaluation, eligible participants will be randomly assigned to one of two arms: the SSI (n=30) or the waitlist control (n=30).

Inclusion Criteria. (A) Be between ages 7 and 17 years; (B) endorse clinically elevated anxiety symptoms on either parent or youth report, as indicated by a score $\geq$ 25 on the Screen for Child Anxiety and Related Emotional Disorders-Child or Parent Versions (SCARED-C/P).

Exclusion Criteria. (A) parent report of past diagnosis of Autism Spectrum Disorder, Intellectual Disability, Bipolar Disorder, Tourette's Disorder, Psychotic Disorders, or Substance Use Disorders; (B) show high likelihood of hurting themselves or others; (C) not having access/connectivity needed for telehealth video conferencing to complete the module.

Procedures

Pilot Phase. Because our module integrates existing strategies and content found in evidence-based CBTs (see SSI Module below), our pilot phase prioritizes user experience (youths, parents) over expert content review. We will identify N = 5 families on our waitlist and administer the SSI module content to each youth-parent dyad. In cognitive response interviews, we will use verbal probing to ask youths and parents to provide feedback on module content (e.g., "what strategies do you find most helpful?, "which strategies were more difficult to understand?" , "was there anything you disliked about the module?"), duration (e.g., "did you find the length of the module to be appropriate?"), and graphics (e.g., "was the module visually stimulating?", "what would help make module more interesting to view?"). We will use data obtained in these interviews to further refine the SSI module, ensuring clear and simple language that is accessible and engaging to youths and parents.

Test Phase. Upon contacting our outpatient clinic, parents will complete a screener to assess inclusion/exclusion criteria. Eligible youth and parents will then be presented with web-based assent/consent forms. Families who provide consent/assent will then complete the PRE evaluation consisting of demographics, SCARED-C/P and Child Anxiety Impact Scale – Child and Parent Versions (CAIS-C/P). Following completion of the PRE evaluation, families will be randomized immediately to either the SSI or waitlist control. Parents of the youth randomized to the SSI will receive a secure link via email containing the module and will be instructed to open it immediately. Both parent and youth will participate in the interactive module simultaneously. After completing the SSI, families will be granted access to view the module video an unlimited number of times and access to reference guides that summarize the module content.

Parents and youth will complete a POST evaluation one week after PRE and a Follow-Up evaluation four weeks after PRE. The POST and Follow-Up evaluations will consist of the same measures as the PRE evaluation, plus the Program Feedback Scale (PFS) and Client Satisfaction Questionnaire – 8 (CSQ-8) at POST and the Treatment Utilization Questionnaire at Follow-Up.

SSI Module

The module contains video segments presenting psychoeducation content and evidence-based practices for managing/reducing anxiety. Interactive exercises and comprehension questions are embedded throughout the module to

solidify understanding of concepts and correct misunderstandings. The module includes 4 main elements based on evidenced-based practices for managing/reducing anxiety (Higa-McMillan et al., 2016) and practices in single session intervention design (Schleider et al., 2020a).

1. Psychoeducation on the tripartite model of anxiety—how anxiety manifests itself through thoughts, feelings, and behaviors.
2. Psychoeducation and practice on self-regulation strategies to manage physiological manifestations of anxiety (i.e., feelings). Families will be introduced to "staying in the moment" and "relaxation strategies" and will have the opportunity to practice implementing the chosen strategy.
3. Explanation and practice of cognitive restructuring of anxious thoughts into neutral or realistic thoughts.
4. Evidence-based strategies on how parents can support their children in managing their anxious feelings and thoughts.

Measures

Primary Outcome.

Youth anxiety outcome measure completed by parents and youths. Screen for Child Anxiety Related Emotional Disorders—Child and Parent Versions (SCARED-C/P; Birmaher et al. 1997). The SCARED, child and parent versions, are 41-item rating scales that assess anxiety symptom severity. Items are rated on a 3-point Likert scale ranging from "Not true or hardly ever true" to "Very true or often true".

Primary Outcomes.

Youth anxiety impact measure completed by parents and youths. Child Anxiety Impact Scale – Child and Parent Versions (CAIS-C/P; Langley et al., 2004). The CAIS, child and parent versions, assess the impact of anxiety symptoms on the psychosocial functioning of youth. Items are rated on a 4-point Likert scale from "Not at all" to "Very much."

Intervention Acceptability measure completed by parents. The Program Feedback Scale (PFS; Schleider et al., 2020b). The PFS assess acceptability and user perceptions of web-based single session interventions. Seven items are rated on a 5-point Likert scale, ranging from "1" to "5" and participants are asked to share what the liked and what they would change about the intervention in an open-response format. A mean score of ≥3 indicates acceptability and positive program evaluation.

Treatment Satisfaction measure completed by parents and youths. The Client Satisfaction Questionnaire— 8-item version (CSQ-8; Larsen et al. 1979). The CSQ-8 is a widely used measure of satisfaction with mental health services (Sitzia, 1999).

Treatment Utilization measure completed by parents. Because families sometimes initiate alternative treatments during clinical trials, we will collect data on youths' usage of medication and/or psychosocial treatment at any point during their participation (Kolko, 2000). Additionally, we will collect data on whether or not families opted to remain on the treatment waitlist.

STATISTICAL ANALYSIS PLAN

Data management protocols will be used to ensure data integrity. Missing values will be estimated using full information maximum likelihood where applicable. A Holm modified Bonferroni correction will be used to control experiment wise error rate.

Aim 1: To examine the influence of the SSI on anxiety and anxiety impact (impairment), we will use two-way analyses of covariance in a structural equation modeling (SEM) framework (Rausch et al., 2003). We will use a maximum likelihood estimator with robust standard errors (MLR) as implemented in the MPlus 8.8 statistical software program. In each model, participant age, treatment condition, and the PRE-score on the outcome variable will be included as covariates. Robust likelihood ratio tests will be used to examine differences between PRE and POST mean scores and POST and FOLLOW-UP mean scores).

Aim 2: To examine acceptability, we will examine total mean scores of parents' responses on the PFS. A mean score ≥3 indicates acceptability and positive program evaluation. To examine satisfaction, we will examine youth and parent total mean scores on the CSQ-8. Consistent with past studies (Larsen et al., 1979; Smith et al., 2014), we will categorize overall satisfaction ratings as ''poor'' (score = 8–13), ''fair'' (score = 14–19), ''good'' (score = 20–25) and ''excellent'' (score = 26–32).