Study Title: Digital delivery of parent training for disruptive behaviors: Increasing Access to Care

HIC Protocol Title: Cognitive-Behavioral Therapy for Disruptive Behavior in Children and Adolescents
*Note: Study is included within a broader HIC Protocol

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I. Significance and Specific Aims: Disruptive behaviors are among the most common reasons for mental health referral in children, and among the most costly childhood conditions.[1] One-third to one-half of children with disruptive behavior disorders also meet criteria for ADHD, and comorbidity typically worsens the prognosis.[2,3] Parent training programs are clinically effective in the treatment of children's disruptive behaviors, and are included in the recommendations set forth in AACAP and AAP treatment guidelines. However, such behavioral treatment is inaccessible to most families in need.[4] Barriers include distant location, high cost, parents' limited time availability, lack of trained staff, stigma and skepticism of the pediatric mental health system.[4] The underutilization of parent behavior management training for disruptive behaviors was identified as a practice gap by AACAP in 2017.[5] Despite AACAP and AAP guidelines, children are often prescribed psychotropic medication without evidence-based behavioral interventions such as parent training.[6] To overcome some of these barriers to high quality care, online delivery of evidence-based parent management training (Digital Parent Training (DPT)) has been developed.[7] While most DPT interventions have demonstrated feasibility and acceptability, the majority provide only self-guided static content without clinical guidance, or the capacity for 'dose-adjustment' or gradual escalation of care based on participants' needs.[8] Thus, existing web-based approaches miss the opportunity to identify treatment obstacles early and to refer children to a higher level of care if needed. We propose to test a model of interactive DPT (iDPT) for disruptive behaviors and irritability in young children that augments traditional digital parent training with interactive clinical guidance and consultation. Content for this iDPT approach closely follows core principles and techniques of parent-training methods that have been thoroughly tested in clinical trials at the Yale Child Study Center.[9-11] Through the iDPT program, clinicians will provide parents with support and guidance through "in-app" asynchronous messaging, scheduled video-conferencing and can facilitate referral to the Yale Child Study Center Outpatient Clinic when necessary. Our long-term goal is to run a large RCT to study the clinical efficacy of interactive DPT for disruptive behaviors in children across multiple sites and populations. We must first establish acceptability and feasibility of this approach with an open trial before proceeding to a larger RCT.

Specific aim #1: Examine acceptability and feasibility of iDPT in children with clinically significant levels of irritability and disruptive behavior, ages 4 to 9 years. Acceptability and feasibility will be assessed by percentage of enrollment, completion of the online modules, and the Patient Satisfaction Questionnaire (PSQ).[6]
We hypothesize that $\geq$80% of enrolled subjects will complete all of the online modules and attend 2 of the 3 videoconferencing sessions. We hypothesize that the majority of parents will rate the iDPT as acceptable based on the Patient Satisfaction Questionnaire (PSQ), as evidenced by an average score of 3.0.

Specific Aim #2: Analyze the effect of iDPT on child disruptive behaviors as measured with the Disruptive Behavior Rating Scale (DBRS).[12]
We predict that children whose parents complete the intervention will demonstrate a significant decrease in disruptive behaviors as assessed by the Disruptive Behavior Rating Scale (DBRS).

III. Background and Rationale: Disruptive behavior disorders in children include conduct disorder, oppositional defiant disorder, and disruptive behavior disorder not otherwise specified. According to the Centers for Disease Control approximately 3.5% of US children have a diagnosable disruptive behavior disorder.[13] Nearly 30% of children who present oppositional defiant behaviors develop a conduct disorder.[14] Those who present conduct problems between 7 to 9 years of age are at significantly elevated risk of poor outcomes in adulthood including higher likelihood of committing crime, substance dependence, mental

health problems and relationship difficulties, even after controlling for confounding factors.[2] A sub-population that is in higher need of treatment are children with ADHD. This is because nearly 50% of children with ADHD have co-occurring disruptive behavior disorders, and this worsens clinical prognosis.[1,2] The gold standard for prevention and treatment of behavioral problems in children is parent training, a systematic approach to help parents manage their children's disruptive behaviors.[15] Nevertheless, parent participation in in-person treatment is estimated between 10-34%, and those who enroll attend 35-50% of sessions.[16] Parent-related barriers to participation include cost, schedule conflicts, transportation, need for child-care, and other competing family demands. Provider-related barriers include lack of trained staff, space and limited resources to provide families with parent training.[17-19] Recent NIMH announcements have emphasized the priority of using technology to disseminate evidence-based practice.[20]

In order to improve accessibility to evidence-based treatments, digital delivery of parent training interventions has been explored by several groups. A recent review of available digitally delivered interventions indicates that it is efficacious and demonstrates potential for increased accessibility among families of children with disruptive behaviors.[8] To the best of our knowledge, only one other intervention provides individualized parent training to target the problem behaviors identified by parents.[21] This protocol investigates a new model of DPT that is augmented with individualized goal-identification and clinical guidance with video-conferencing. In addition, the proposed program is the only one of its kind that can be accessed via mobile devices as well as on computers, which may further increase acceptability among parents. A dose-adjustment component will not be tested in the proposed pilot trial. However, it will be an important element of the intervention in future trials, as it could help funnel the most severe cases to clinical settings and thus optimize use of resources. It is necessary to conduct an open trial, without a comparison group initially, to establish acceptability and feasibility. If this pilot trial demonstrates acceptability and feasibility of online behavioral parent training with an integrated personalized component, it will provide the investigators preliminary data to apply for an NIMH grant to test this intervention in a larger Randomized Control Trial.

IV. Research Plan

Participants. In this pilot study, we will enroll 16 children with disruptive behaviors disorder recruited at Yale Health and Yale Medicine Pediatric Outpatient Services.

Inclusion criteria: i. Child is ages 4 to 9 years old, ii. Child meets diagnostic criteria for one of the Disruptive Behavior Disorders or Disruptive Mood Dysregulation Disorder, iii. Parents have access to a mobile device and/or computer device, iv. Parents speak English as native language, v. Affective Reactivity Index parent-report score is above 3.6, which is the mean for children with severe irritability, vi. Families agree not to initiate new mental health treatments for the duration of this study. <u>The sample will be enriched with children with ADHD, by ensuring that at least 50% of participants meet criteria for ADHD based on parent and teacher ratings above 1.8.</u>

Exclusion criteria: i. Child is non-verbal or minimally verbal; *or* ii. Child's tantrums or aggressive behavior pose significant risk of injury or property damage and require immediate treatment; *or* iii. child has untreated medical or psychiatric disorder that requires immediate intervention; *or* iv. parents have previously received parent-training.

Design This is an open, feasibility pilot study of interactive digital parent training for children with disruptive behaviors. iDPT is a novel web-based, interactive parenting intervention for disruptive behavior in children. Following the principles of testing feasibility and acceptability as the first step in developing new psychosocial interventions[17], a comparison group will not be included in this pilot trial. Participants will be recruited through the Yale Health and Yale Medicine Pediatrics outpatient services. Parents who choose to enroll will undergo telephone screening, and if likely to be eligible, they will be invited to an in-person

clinical characterization visit. As an incentive to participate, parents will be offered $50 upon completion of in-person clinical characterization visit and $50 for attending final study visit, and parking compensation.

Telephone Screening and Clinical Characterization. Screening and characterization will be conducted to ensure eligibility and establish a baseline for the Disruptive Behavior Rating Scale, the outcome measure. Parents who express interest in the study will be contacted by the lead clinician (the Principal Investigator). A brief description of the study will be provided, and eligibility will be determined based on the inclusion and exclusion criteria that do not require clinical assessment. If the subject is deemed likely to be eligible, they will be invited to attend an in-person clinical characterization assessment at the Yale Child Study Center Outpatient Clinic. At the in-person characterization visit, a description of the study will be provided. Formal consent will be obtained from the parent and assent from the child. The Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL)[22], a structured interview will be conducted with parent and child by the Principal Investigator, to establish Diagnostic and Statistical Manual of Mental Disorders, 5th ed. (DSM-5) diagnoses. The items, which are drawn directly from DSM-IV, are scored from 0 (never) to 3 (very often) and can be scored in two different ways: symptom count (number of items rated 2 or 3) and symptom severity (sum of the scores for the specific diagnostic subscale). Of interest in the current study are the following subscales: attention-deficit/ hyperactivity disorder [ADHD; 18 items], oppositional defiant disorder [ODD; 8 items], pervasive developmental disorder [PDD; 12 items], and the 16-item anxiety scale. In addition, parents will complete the Affective Reactivity Scale to select children whose disruptive behaviors are above 3.6, the mean for children with severe irritability.[23,24] Parent and teacher scales of the Swanson, Nolan and Pelham Questionnaire (SNAP) will be used to ascertain ADHD diagnosis. This is to enrich the sample with 50% or more children with ADHD, a proportion of the sample that is reflective of prevalence in children with disruptive behaviors.[24] In addition, the Child Symptom Inventory will be administered. It is a 108-item parent report on child behavior.[25] At this visit, the DBRS will be administered to ascertain eligibility and obtain a baseline of disruptive disorder symptom severity. Upon completion of the assessment, if the subject is deemed eligible to enroll in the study, parents will be provided with login and password to access the iDPT program.

Intervention. The iDPT that will be utilized is on an online platform called MindNest Health. This platform is a parent-focused learning management system that was accepted into the Yale Entrepreneurial Institute Venture Creation Program. The iDPT program comprises 8 modules that closely adhere in content to evidence-based Parent Management Training (PMT. The digital platform has undergone comprehensive user testing with parents of children with disruptive behaviors to assess the software functioning. The content is delivered in parent-friendly and accessible language and the parent training principles are illustrated using animated simulations of a parent and child, with voice-over from a narrator. A demo is available at https://dev.mindnesthealth.com/#/demo. The modules are delivered as follows: **Weeks 1-2:** The first two modules ("Introduction to tantrums" and "The ABC's of Behavior") provide background and foundational concepts of behavioral management. After completion of module 2, parents will be scheduled for a 30-minute videoconference with the lead clinician to identify specific disruptive or noncompliant behaviors in their child that parents want to decrease. **Weeks 3-4:** Modules 3, 4, and 5 teach parents antecedent management skills. Parents will be instructed to choose different skills, one skill at a time, to try out at home for 1 week, with clinician support via in-app messaging. After 2 weeks of practice, during videoconference #2, the lead clinician will address any barriers to implementation and instruct parents on tracking their child's behaviors and progress. **Weeks 5-6:** Modules 6, 7, and 8 address reinforcement of positive behaviors. Parents will be instructed to try out several reinforcement techniques for 2 weeks. The final videoconference #3 will address barriers to implementation, goal tracking, and further instruction for continued implementation.

At the end of the study, participants will be asked to complete the *Patient Satisfaction Questionnaire (PSQ)*[6], which is an 8-item measure of satisfaction with treatment. Parent and child versions are available, and both will be administered. Items such as "how satisfied were you with the treatment you have received?" and "would you recommend this treatment to a friend?" are rated on a 4-point scale with higher scores reflecting greater satisfaction. PSQ has excellent reliability and has been used in feasibility treatment studies of internet delivered behavioral interventions for pediatric populations.[26,27] We predict (Hypothesis 1) that parent ratings of patient satisfaction with this iDPT will be high as evidenced by average score of 3.0 on the PSQ. In addition, families will complete the DBRS to assess post-intervention change in disruptive behaviors. If families wish to remain in contact for continuity of care, they will be referred to the Yale Child Study Center Outpatient Clinic for follow-up.

Data Analysis: **1. Acceptability and Feasibility Analysis.** Feasibility will be examined with three measures: a) completion of 80 or more of the modules and b) attendance to two of the three videoconferencing sessions. Parent's perspective on acceptability of the intervention will be assessed utilizing the Patient Satisfaction Questionnaire. We will deem the treatment acceptable if parents select responses 'Slightly Agree' or 'Agree' on the 15 Acceptability factor items. This will be reflected as a score of 3.0 or above on the PSQ. We will use fixed effects analysis of variance to compare session attendance/online course completion and scores on the PSQ. **2. Child Outcome.** At baseline and endpoint, parents will complete the DBRS. We will compute pre-to post-treatment differences on the DBRS and examine the number of subjects showing clinically meaningful reduction in the DBRS total score. By convention, a DBRS score of 12 is considered clinically significant. A 35% reduction in DBRS score is considered "improved" and a 50% reduction is considered "much improved." Given that traditional parent-training interventions show clinically significant improvement in approximately 60% of participants, we predict that 10 of 16 subjects in this open study (63%) will show a clinically meaningful reduction of the DBRS score. Because the primary aim of this study is to determine feasibility, the data analysis for the second aim of estimating the magnitude of change in the continuous outcome measure, DBRS, will be straightforward. We will use paired-samples t-test to examine the differences between baseline and endpoint DBRS scores. Based on previous studies from our group[23], we can project for a change from DBRS mean score of 15 (SD=5) at baseline to 10 (SD=5) and endpoint. This difference can be detected with statistical power > 80% and alpha level < 0.05 in a sample of 16 subjects.

Feasibility**:** Dr. Diaz Stransky, the principal investigator and lead clinician, is a Solnit adult and child psychiatry fellow at the Yale Child Study Center who will be in her Post-graduate year 5 of training. She has completed a course of training on PMT for child psychiatry fellows conducted by Dr. Sukhodolsky and has extensive experience of providing PMT to families of children with disruptive behavior. Her research has been also focused on parent-training interventions aimed to improve child mental health. She is fluent in English, Spanish, Portuguese and French and could inform future versions of this program. Her mentors will be Dr. Denis Sukhodolsky and Dr. David Grodberg. The principal investigator will meet weekly with both mentors for supervision. Dr. Sukhodolsky is associate professor in the Yale Child Study Center and a licensed psychologist who has conducted large randomized control trials of parent-management training for disruptive behavior in children. Dr. Grodberg is a board-certified child psychiatrist, Director of the Yale Child Study Center Outpatient Clinic and founder of MindNest Health. Both mentors are trained to research fidelity in parent-management-training.

Relevance to AACAP Pilot Award Mission: The principal investigator is a talented young physician-scientist with significant protected research time, pursuing an academic career in this field. The intervention is an innovative solution that may help a major child mental health problem. This study can provide the principal investigator with pilot data for a larger research award.

V. Project Timeline

August 2018: Recruitment and Screening will begin

August 2018:
- Participant enrollment will begin
- Pre-intervention data collection will begin

August 2018 – July 2019:
- Intervention delivery for enrolled participants
- Post-intervention data collection for participants after completing the intervention
- Study team meetings will be held weekly with Principal Investigator and mentors

May 2019:
- Participant enrollment will stop at the end of May
- Preliminary Data Analysis for New Research Poster submission

July 2019: Last participants will complete intervention by the end of July 2019

August-September 2019:
- Data Analysis
- Preparation of poster for presentation at annual meetings for AACAP, American Psychiatric Association, American Academy of Pediatrics.
- Final report writing.
- Preparation of grant proposal for NIMH funding.

October 2019: AACAP Poster presentation

VI. Budget and Budget Justification

PERSONNEL					
Name	Role on Project	% Time	Salary Request	Fringe Benefits	Amount Requested
Andrea Diaz Stransky	Principal Investigator	40 %	$0	$0	*Not allowed* $0
Denis Sukhodolsky	Primary Mentor	0 %	$0	$0	$0
David Grodberg	Secondary Mentor	0 %	$0	$0	$0
To Be Named	Post Grad Associate	25%	$9,500	$2,898	$12,398
				SUBTOTAL	$12,398

MATERIALS			
Description	Quantity	Unit Cost	Amt. Requested
(DBRS-1) Disruptive Behavior Rating Scale Kit	1	$ 208	$ 208
(DBRS-3) Parent Version Response Forms	1 package (50)	$35	$ 35
Child Symptom Inventory	1 package (50)	$63	$ 63
Study payment for each session	33	$60	$1980
AACAP Travel Expenses			$316
		GRAND TOTAL	$15,000

Personnel: **Andrea Diaz Stransky, MD** – (Principal Investigator, 40% effort) – Dr. Diaz Stransky is a PGY-4 Resident in a six-year Integrated Training Program in Adult Psychiatry, Child Psychiatry, and Research at the Yale Child Study Center (YCSC). As a PGY-5, Dr. Diaz Stransky will be funded on the Child Study Center's institutional training grant T32 MH018268, which provides full-time stipend support and allows her to work on the research project(s) of her choice. Dr. Diaz Stransky will carry out the baseline assessment of participants and provide videoconference sessions for all the participants. She will conduct the statistical analyses, interpret the results, write the manuscript, and present findings at national psychiatric meetings.

Denis Sukhodolsky, PhD (Primary Mentor) – Dr. Sukhodolsky is an Associate Professor at the YCSC and is the PI of an R01 study that uses cognitive-behavioral therapy to examine the neural circuitry of aggression in children across diagnostic categories. Dr. Sukhodolsky will oversee the intervention, including screening, videoconferencing and any other interactions with participants as the need arises. He will supervise the statistical data analysis, interpretation of results and preparation of the manuscript. As a mentor, there is no measurable effort provided.

David Grodberg, MD – (Secondary Mentor)- Dr. Grodberg is a board-certified Child and Adolescent Psychiatrist and serves as medical director of the YCSC Outpatient Clinic. He is the creator of the MindNest Health Platform. He will provide mentorship and supervision to Dr. Diaz-Stransky. He will facilitate liaison between the research team and the MindNest Health team for any technology support or project management needs. As a mentor, there is no measurable effort.

To be named Postgraduate Associate – (Postgraduate Associate, 25% Effort) – The Postgraduate Associate will schedule in-person baseline and endpoint assessment visits, collect paper-and-pencil rating forms and enter data in the data-management system.

Materials: Payment to participants for each visit considers $50 dollars per 15 participants for two visits, as well as additional visits by participants who attend the first visit but do not qualify for enrollment. In addition, $10 dollars per visit for parking will be included. The Child Symptom Inventory will be administered at the first visit and the Disruptive Behavior Rating Scale will be administered at each visit. Thus, one package of 50 response sheets will be needed of each scale.

VII. Exclusion of Women and Minorities

This protocol does not exclude women or minorities from the study.

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