**Request to Resume Human Subjects Research Activities for Targeting Attention Orienting to Social Threat to Reduce Social Anxiety in Youth**

**Sponsor Protocol Number:** R01 MH119299

**IRB Protocol Number:** IRB-19-0109-AM05

**Principal Investigator:** Jeremy Pettit

1. A brief summary of the grant including the goals of the project, benefit to the families, number of persons affected, funding source and amount.
	1. **Goal**: The goal of this project is to provide a rigorous test of attention bias modification treatment (ABMT) as a treatment for social anxiety disorder (SAD) in children ages 9.5 to 14.5 years. SAD is prevalent, chronic, and impairing. It predicts poorer educational outcomes and the onset of depression, substance use, and suicidal behaviors. Response rates to evidence-based treatments such as cognitive behavior therapy are markedly lower for SAD than other anxiety disorders. Alternative treatment options are therefore critically needed for children with SAD.
	2. **Benefits.** In preliminary studies, ABMT has produced significant decreases of medium effect size in anxiety symptoms and the comparator control arm has produced significant decreases of small effect sizes in anxiety symptoms. Based on these findings, we anticipate that participants in this project will directly benefit from their participation and experience reductions in social anxiety symptom severity and related impairment.
	3. **Number**: This is a multisite project clinical trial. We will enroll 130 children with SAD at the FIU site. An additional 130 will be enrolled at the Yale University site (pending reopening of on-campus human subject research by Yale Office of Research). Several hundred families contact our program, the FIU Child Anxiety and Phobia Program, each year seeking mental health services for youth anxiety. These families complete a standard phone screen and intake interview prior to initiation of services. Families who meet preliminary eligibility requirements for the study based upon the phone screen will be informed about this new treatment study, and if interested, will be scheduled for a Zoom interview to learn more about the study, provide consent, and complete the intake interview. We anticipate approximately 5 participants would come to campus weekly.
	4. **Funding Source:** National Institute of Mental Health R01 MH119299
	5. **Amount of Funding:** $1,002,531 in year 2 of the grant; $5.2 million total over 5 years. We are currently in year 2 of the project. We had almost completed year 1 in March at the time project activities were stopped due to COVID19.
	6. **Why now?** Although one might assume SAD causes less impairment now that children are largely attending school remotely, anecdotally families are reporting the same types and levels of impairment in virtual settings (e.g., child refusal to log into zoom class, refusal to show face during zoom, refusal to ask or answer questions, etc.). These impacted families express a strong desire for help, especially with a new school year beginning soon. That is, these children are suffering from an anxiety disorder and the intensity of their suffering and impairment is about to worsen when school starts, whether remotely or in person. We expect this clinical trial will directly benefit them and contribute to knowledge that will benefit children who suffer from SAD worldwide.
	7. **Why in person?** We propose to do everything we can remotely, including recruitment, interviews, and questionnaires. We propose 2 in-person activities: (i) treatment delivery and (ii) EEG/eye-tracking data collection.
		* 1. The treatment involves computer-administered training that requires repeated responses from the participant by clicking a mouse button. We approached our NIMH Program Officer about developing a method for remote delivery of the training. She did not approve the development of remote delivery because it would introduce a confound into this large, definitive trial of ABMT for SAD. Prior preliminary research has found home-based ABMT to be less effective than ABMT delivered in the clinic.
			2. EEG and eye-tracking are the primary ways we measure the treatment target, attention to social threat. These measures must be collected in person, placing an EEG net on participants and recording participants’ eye movements using special camera/equipment.
	8. **Measures to reduce risk to children, parents and FIU staff**:
		* 1. Initial background information, all interviews, and all questionnaires/surveys will now be administered remotely using telephone and Zoom.
			2. For in-person activities, parents arrive on campus and notify project staff who will come to their parked car and complete the questions on the FIU PP3 app. If all the answers are answered correctly, children will be escorted into AHC 5 Room 124 for EEG/eye-tracking or AHC 1/ACH 5 first floor clinic rooms for treatment sessions, avoiding any contact with others. Parents will be asked to wait outside or in their cars. Participants will be required to have a facial covering and if they do not have one, we will provide a surgical mask. The EEG/eye-tracking sessions will last approximately 60 minutes. This is the least amount of time that we can spend on each subject and still be effective. The treatment sessions will last approximately 15 minutes and upon completion participants will be escorted back to their parents outside/at car.
			3. Participants and project staff will be wearing a facial covering at all times. Further, EEG staff will be wearing an N95 mask, face shield, laboratory coat, and gloves at all times when interacting with participants. We will thoroughly and regularly disinfect all surfaces before and after every session according to EHS approved protocols. See attached protocols for details.
			4. During EEG sessions, the tech will be within arms’ length of the participant while placing the EEG net (approximately 10 minutes). Once the net has been placed, the tech will move away from the participant and stand in the hallway outside the room, observing the participant through the open door from a distance greater than 10 feet. The participant will sit in a chair facing a table to complete a computer task (approximately 20 minutes). After the task is completed, the tech will return to the participant and remove the EEG net (1 minute). The tech will then instruct the participant on how to complete two eye-tracking tasks and will calibrate the eye-tracking tasks. While giving instructions and calibrating the tasks, the tech will sit behind the thick floor to ceiling curtain separating the tech from the participant (approximately 5 minutes). Then the tech will again leave the room and stand in the hallway outside the room, observing the participant through the open door from a distance greater than 10 feet. The participant will complete two eye-tracking tasks (approximately 25 minutes). The session will then end. The total duration of the session is about 60 minutes. In total, the participant and tech will be in the room together for approximately 15 of the 60 minutes. For the other 45 minutes, the tech will be in the hallway observing the participant through the open door. The tech will always be wearing full PPE and the participant will always be wearing a face covering. See attached EEG protocol for full details.
	9. **Summary** – This project directly benefits children (and families) who are suffering from impairing levels of social anxiety. These children show poor overall response to standard treatments, heightening the need for an alternative treatment like ABMT. The results of this project have potentially significant benefit to individuals, families, and larger society in the form of a novel intervention for promoting the well-being of children with impairing levels of social anxiety.