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TITLE: **Behavior Therapy for Irritability and Aggression in Adolescents with Autism**

PRINCIPAL INVESTIGATOR: **Denis Sukhodolsky**

CONTRACTING ORGANIZATION: **Yale University, New Haven, CT**

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| 14. ABSTRACT Approximately 50 percent of children with Autism Spectrum Disorder (ASD) exhibit irritability and disruptive behaviors such as tantrums, noncompliance, and aggression. If present in childhood, aggression tends to persist into adolescence and adulthood and contribute to disability over and above the core ASD symptoms. The purpose of this study is to investigate the clinical efficacy of a novel intervention, Behavior Therapy for Irritability in Adolescents with ASD (BTIA). Specifically, this is a randomized controlled trial of BTIA vs. Psychoeducation and Supportive Therapy (PST) control condition in adolescents, ages 12 to 19, with ASD and significant levels of disruptive behavior. During the third year of the project period, the study was successfully continued and it is currently conducted in accordance with the study protocol. | | | | | |
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1. INTRODUCTION

This is a randomized controlled trial of Behavior Therapy for Irritability (BTIA) in 12 to 19-year-old adolescents with autism spectrum disorder. There are four primary goals in this study. Goal 1 is to evaluate the efficacy of BTIA vs. Psychoeducation and Supportive Therapy (PST) for reduction of irritability and disruptive behavior in adolescents with ASD in a randomized controlled trial. Goal 2 is to test the effects of BTIA on adaptive behavior using the Vineland Adaptive Behavior Scales-3 edition (Vineland-3) administered at baseline, endpoint, and 6-month follow-up. Goal 3 is to test durability of treatment gains over a 6-month follow-up period. And goal 4 is to explore the moderating effects of subject demographic and clinical characteristics at baseline on response to BTIA vs PST. BTIA consists of 15 ninety-minute weekly sessions that are delivered by behavioral therapists using a detailed manual that targets both common and ASD-specific mechanisms of irritability. It includes structured, illustrated activities for teaching emotion regulation and problem-solving skills to the adolescent; a functional assessment to identify unique triggers of disruptive behavior; and a parent component that teaches antecedent management and reward strategies. PST is used as a control condition because during adolescence, many individuals with ASD may become more acutely aware of their differences from peers and may benefit from psychological support. PST also consists of 15 weekly sessions and will be conducted by experienced therapists using a structured manual. Regarding potential clinical impact of this study, irritability and disruptive behavior are common in children and adolescents with ASD, tend to persist into adulthood, and contribute to disability over and above the core ASD symptoms. There is also a major gap in treatments for adolescents on the autism spectrum. This study is conducted to evaluate the clinical effects of a novel intervention, Behavior Therapy for Irritability in adolescents with ASD (BTIA). If proven effective, BTIA will provide a useful treatment option for adolescents with ASD complicated by behavioral problems.

2. KEYWORDS

Autism Spectrum Disorder; Adolescents; Irritability; Disruptive Behavior; Treatment; Cognitive-Behavior Therapy; Behavior Therapy for Irritability in Adolescents; Randomized Controlled Trial

3. ACCOMPLISHMENTS

What were the major goals of the project?

The major goals of the project during the second year were accomplished in accordance with the approved SOW and included the following tasks: 1) Maintaining human subjects review and approvals; 2) Conducting community outreach and subject recruitment; 3) Conducting subject characterization and treatment-outcome study assessments; 4) Delivery of study interventions; and 5) Carrying out data and safety monitoring.

What was accomplished under these goals?

Task 1, maintaining IRB approvals This protocol is approved by the Yale Institutional Review Board (IRB) and by the U.S. Army Medical Research and Development Command (USAMRDC), Office of Research Protections (ORP), Human Research Protection Office (HRPO). During the third year of the study, the Yale IRB has approved our amendment to add Yale MyChart recruitment mechanism to our study on March 16, 2023, and to add new study personnel on June 6 and August 03, 2023. The Yale IRB also conducted continuing review and re-approved this protocol on December 5, 2022, and the USAMRDC ORP HRPO also conducted continuing review and reapproval of this protocol December 21, 2022.

Task 2, community outreach and subject recruitment. During this year, 20 subjects have been consented and evaluated and 15 meet inclusion and were randomized. Of the five subjects who were not randomized, two declined participation due to scheduling consideration, two subjects presented with more pressing clinical needs and were referred for appropriate services, and one subject did not meet inclusion criterion for presence of irritability symptoms.

During this year, we have continued our recruitment efforts with 13 in-person events as well as mailouts and remote efforts. Regarding in-person events, 1) we participated in the Benhaven Autism Walk, held on

September 25, 2022. As co-sponsors of this event, we had a dedicated table that facilitated distribution of the study flyers to potentially interested families and received logo exposure on event merchandise, email blasts, social media releases, and recognition on the event's website. 2) We co-sponsored the 2nd Annual Fall conference for Northeastern Applied Behavioral Analysis, which was held virtually on October 1, 2022. Through this event, our study was recognized in the opening and closing statements, featured in social media posts, and a PowerPoint slide displaying our study information was played during breaks. 3) On October 2, 2022, we attended the Autism Speaks Westchester Greater Hudson Valley Walk hosted by New York Presbyterian Hospital. 4) We attended the Connecticut Women's Expo from October 15-16, 2022, as an exhibitor and handed out study flyers to participants. 5) We attended the Autism Speaks Connecticut Walk on October 23, 2022, which featured sponsorship recognition on promotional materials, a social media post, and a booth and tent within the event space. 6) We attended the Connecticut Association of School Based Health Centers on November 8, 2022, where we distributed study flyers to school nurses and health workers in the exhibitor hall and discussed the study with providers who were potentially interested in referring subjects. 7) We participated in the Connecticut Association for Behavior Analysis's 19th Annual Conference (March 9-10, 2023) in Hartford, CT that was attended by 600 providers. Our information was displayed at the sponsor table and included in a scavenger hunt for attendees interested to learn more about research opportunities. 8) We sponsored the Wallingford Special Education Resource Fair on April 25, 2023 which included a front table at the event and a full-page advertisement in their resource booklet. 9) On April 28, 2023, we attended the High School in the Community Health Resource Fair in New Haven, CT in which we connected with local high schoolers about our study and mental health. 10) Our lab participated in the Autism Awareness event at the capitol building in Hartford, CT, on April 28, 2023. 11) We sponsored the local New Haven Walk for Autism on April 29, 2023 which featured our study information as a full-page advertisement in the resource book and a table at the event. Our most recent recruitment events included 12) tabling at the New Haven Family Stroll and Festival on May 20, 2023 and 13) co-sponsoring the Autism Services and Resources Connecticut's annual Walk for Autism Resource and Employment Fair on May 21, 2023. Dr. Sukhodolsky also gave a lecture to the Yale Working Women's Network on the topic of "Helping Children on the Autism Spectrum Build Resilience" on April 19, 2023 in which he shared study information and details.

We have conducted four informational mailouts along with other remote outreach efforts. We sent out 255 mailers to school psychologists and social workers working in 125 Connecticut public and private middle and high schools as well as 70 mental health professionals and 351 pediatricians working in CT. We sent out letters to 68 school psychologists working in CT specialized and therapeutic schools. Each mailer consisted of a personalized envelope containing a letter, flyer, and brochure of the study to be advertised in school offices and disseminated among families. We also periodically boosted our study flyer advertisement on Facebook to a targeted audience and emailed various Connecticut autism organizations and non-profits in November to ask that they advertise our study in their newsletters.

In addition to these ongoing recruitment and outreach efforts, we connected with the Yale Center for Clinical Investigation (YCCI) to expand our recruitment efforts through their platforms including outreach to Yale Medicine clinics. Our study is now listed in the "YCCI Help Us Discover" research database under "Child/Parent" and "Behavioral Health" studies; this database consists of 14,000 individuals who have expressed interest in volunteering for research studies at Yale, and emails are sent periodically to this database with a list of ongoing studies. YCCI also created a series of infographics about our study for Autism Awareness Month and shared this post on their Facebook page and Instagram. Our team re-posted this infographic to our own social media pages, and further enhanced social media recruitment by boosting targeted advertisements of our study flyer during the months of March and April 2023.

We also connected with YCCI's Cultural Ambassadors Program, a partnership program with the goal of increasing participation of Hispanic and African American populations in clinical trials. In April, we met with the coordinators of the program and representatives (cultural ambassadors) of the local Junta and AME Zion Churches to discuss our study information and how the cultural ambassadors could share our information with their communities. The cultural ambassadors were given our study recruitment flyer to share with their communities; our study information and flyer were shared by the ambassadors to the Connecticut Parent Advocacy Center and a parent advocate. Furthermore, as part of this partnership, Dr. Sukhodolsky and study coordinator Julia Zhong appeared as guests on the Tom Ficklin Radio Show (WNHH 103.5) on April 24, 2023 for a 1-hour discussion with the cultural ambassadors and host Tom Ficklin to discuss "Empowering Adolescents Diagnosed with Autism". During this segment, they discussed diversity issues within autism, mental health, and advertised study information.

We also worked with YCCI to enroll in their Direct to Patient Messaging program via MyChart and EPIC. The Yale Joint Data Analytics Team (JDAT) research team has set up these direct messaging capabilities through the Yale New Haven Health electronic health record system (EPIC) in MyChart to identify potential participants. Potential participants who meet certain demographic criteria based on medical conditions are sent a message about the study trial by the Yale JDAT team through MyChart; if the patient responds that they are interested, research coordinators are given their contact information and can contact interested potential volunteers. Over the course of the past two months, our team has had several meetings with the Yale JDAT research team about the process of enrolling our study in this program. The patient query that was created for our study has identified 2,600 potential patients to be contacted, with 100 messages to be sent to this patient listserv weekly.

Task 3, conducting study assessments. The study's clinical characterization and outcome assessment visits are conducted by a team of highly trained clinicians who are supervised by Dr. Sukhodolsky. There are two 3-hour pre-treatment assessment visits for clinical characterization of ASD, co-occurring psychiatric disorder, IQ, language, and adaptive functioning. Repeated clinical outcome measures of irritability are collected at baseline, mid-point, endpoint and six-month follow up and are conducted by an independent evaluator ("blinded rater"), Mrs. Heidi Grantz, who is not involved in any aspects of treatment delivery in order to protect her blind. Scheduling and running assessment visits on a pre-determined timeline are key to successful administration of any clinical trial. During this year, Ms. Julia Zhong, has served as the study coordinator until July 2023 when she moved to a Ph.D. program in clinical psychology at Suffolk University. We have also hired a new research assistant, Ms. Sydney Anderson, who has been trained on all study procedures and serves as a primary study coordinator.

Task 4, delivery of study interventions. Of the total number of 40 subjects randomized to-date, 36 have completed active phase study interventions and endpoint assessments. Four subjects are currently receiving therapy and eight subjects are scheduled for a 6-month follow up assessment. During this year, the study included three behavioral therapists (Karim Ibrahim, Carla Calvin, and Joshua Snyder) who have been trained by Dr. Sukhodolsky to conduct both study interventions (BTIA and PST) reliably and in accordance with detailed manuals. We have also trained a new study therapist, Ms. Jordan Linde, who has completed all didactic training procedures and served as a co-therapist with Drs. Calvin and Ibrahim during this year. She will be able to carry her own study therapy cases next year under supervision of Dr. Sukhodolsky. This process of training additional therapists allow us the flexibility to offer families evening appointments. Study therapists and Dr. Sukhodolsky have weekly, one-hour supervision meetings dedicated to discussing therapy progress, adherence to treatment manuals, and troubleshooting clinically relevant issues that might be brought up by study participants. All BTIA and PST sessions are videotaped and reviewed for adherence to treatment protocols. There were no unexpected, serious adverse events in this study.

Task 5, conducting data and safety monitoring. Dr. Sukhodolsky carries out clinical monitoring of the study to ensure compliance with the protocol; good clinical practice guidelines; federal, state, and local regulations and institutional policies and procedures; that data are of high quality and integrity; and that the facilities and staffing are adequate for continued study participation.

What opportunities for training and professional development has the project provided?

All postbaccalaureate and postdoctoral trainees at Yale University are required to create an individual development plan (IDP) and to provide annual progress reports for review by, and discussion with, the faculty mentor. Progress reports are then submitted to the Yale Office of Postdoctoral Affairs as a condition of the trainee's reappointment by this Office. All graduate students in the Combined Program in the Biological and Biomedical Sciences as well as all other graduate students supported by federal awards at Yale University are required to create an individual development plan. Students provide updates on their IDP activities as a part of their annual thesis committee meetings, and documentation is retained by the students' graduate programs.

How were the results disseminated to communities of interest?

Denis Sukhodolsky and his lab regularly present at national and local meetings on the topic of treatment of irritability and disruptive behavior in children on the autism spectrum, including:

- 2023 Lecture, Yale University Working Women's Network, New Haven, CT, April 19, 2023, Autism spectrum disorder: Helping child on the autism spectrum build emotional resilience.
- 2023 Presentation, Annual Meeting of the Society of Biological Psychiatry, San Diego, CA April, 27-29, 2023. Altered connectivity in large-scale resting-state networks characterize anxiety in autism. (Poster with Karim Ibrahim, Kevin Wee, Jasmine Hinton, Julia Zhong, Dustin Scheinost and Megan Rutten).
- 2023 Presentation, the annual conference of the International Society for Autism Research (INSAR), Stockholm, Sweden, May 03-06, 2023, Comprehensive therapy for irritability in adolescents with autism: Study design and pilot data, (Poster with lab members Julia Zhong, Josh Snyder, Jordan Linde, Karim Ibrahim and Carla Calvin).
- 2023 Presentation, the annual conference of the International Society for Autism Research (INSAR), Stockholm, Sweden, May 03-06, 2023, Association of irritability with restricted repetitive behavior in children with ASD, (Poster with lab members Megan Rutten, Julia Zhong, Jordan Linde and Carla Calvin).
- 2023 Presentation, the annual conference of the International Society for Autism Research (INSAR), Stockholm, Sweden, May 03-06, 2023, Intolerance of uncertainty is associated with irritability in school-age autistic children, (Poster with lab members Julia Zhong, Megan Rutten, Josh Snyder, Jasmine Hinton and Carla Calvin).
- 2023 Presentation, the annual conference of the International Society for Autism Research (INSAR), Stockholm, Sweden, May 03-06, 2023, Large-scale networks of anxiety in autistic children based on intrinsic functional connectomes, (Poster with lab members Karim Ibrahim, Kevin Wee, Jasmine Hinton, Megan Rutten and Dustin Scheinost).
- 2023 Presentation, the annual conference of the International Society for Autism Research (INSAR), Stockholm, Sweden, May 03-06, 2023, Disruptions in amygdala-prefrontal connectivity are associated with severity of anxiety and modulated by levels of social impairment in autistic children, (Poster with lab members Karim Ibrahim, Anna Pusoc, Kevin Wee, Julia Zhong and Carla Calvin).
- 2023 Presentation, the annual conference of the International Society for Autism Research (INSAR), Stockholm, Sweden, May 03-06, 2023, Disruptions in Amygdala Activation Are Linked to Eye Gaze Processing in Autism: An fMRI Meta-Analysis, (Poster with Iciar Iturmendi Sabater, May Vasishth, Simon Eickhoff and Karim Ibrahim).
- 2023 Presentation, Yale Child Study Center, Research in Progress Seminar, February 16, 2023. Neural mechanisms of cognitive-behavior therapy in autism.
- 2022 Lecture, *Irritability and anxiety in adolescents on the autism spectrum*, Autism Summer Institute, Child Study Center, Yale School of Medicine, New Haven, CT, (July 28, 2022).

What do you plan to do during the next reporting period to accomplish the goals?

This is a 4-year project. We will continue to run the study in accordance with the study protocol. The key activities of the next, 4th year will include subject recruitment, clinical characterization assessment, treatment delivery, and collection of clinical outcome data. We are also hoping to request a no-cost extension to this study after the end of the 4th year to enable increasing the sample size.

4. IMPACT

Nothing to report

5. CHANGES/PROBLEMS

Actual or anticipated problems or delays and actions or plans to resolve them:

Our recruitment efforts in year one was slower than anticipated, unfortunately, due to the Covid-19 pandemic. Human subjects research has been slow across all studies at the Yale Child Study Center. During the 2nd and 3rd years, we have been able to maintain high levels of community outreach that resulted in sharp increase of subjects enrollment. We are optimistic that we will be able to meet our enrollment goals as the recruitment rates for clinical trials such as our study are returning to the pre-pandemic level.

Changes that had a significant impact on expenditures

We reduced personnel effort in Year 1 to reflect slow recruitment due to the COVID-19 pandemic in the hope that we can carry-over the balance to the later study periods when we are able to increase subject recruitment.

6. PRODUCTS

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANZATIONS

What individuals have worked on the project?

| | |
|-----------------------------------|---|
| Name: | Denis Sukhodolsky, Ph.D. |
| Project Role: | PI |
| Researcher Identifier (ORCID ID): | 0000-0002-5401-792X |
| Nearest person month worked: | 3 |
| Contribution to Project: | Dr. Sukhodolsky oversees all aspects of the proposed study, including assurance of regulatory compliance and communication with the funding organization, as well as subject recruitment, clinical characterization. He also provides training and supervision on study interventions to study therapists. |
| Name: | Julia Zhong, B.S. |
| Project Role: | Study Coordinator |
| Researcher Identifier (ORCID ID): | 0000-0002-1809-0572 |
| Nearest person month worked: | 6 |
| Contribution to Project: | Ms. Zhong coordinated recruitment efforts, scheduling assessment visits, and guiding children and their families through characterization and outcome assessments. She prepares all study assessment materials and outreach efforts. In June 2023, Ms. Zhong has trained a new study coordinator, Sydney Anderson, who joined the lab on June 16, 2023. |
| Name: | Sydney Anderson, B.A. |
| Project Role: | Study Coordinator |
| Researcher Identifier (ORCID ID): | 0009-0008-1848-0571 |
| Nearest person month worked: | 1 |
| Contribution to Project: | Ms. Anderson, joined the lab in June 2023 and she will continue to serve as the study primary coordinator. Her responsibilities include coordinating recruitment efforts, scheduling assessment visits, and guiding children and their families through characterization and outcome assessments. |
| Name: | Megan Rutten, B.A. |
| Project Role: | Research Assistant |
| Researcher Identifier (ORCID ID): | 0000-0002-3104-2508 |
| Nearest person month worked: | 1 |
| Contribution to Project: | Ms. Rutten joined Denis Sukhodolsky lab in July 2021, and she has |

been trained on all study procedures to serve as a backup for Ms. Zhong and Ms. Anderson when needed.

Name: **Karim Ibrahim, Psy.D.**
Project Role: Clinical psychologist
Researcher Identifier (ORCID ID): 0000-0002-5401-792X
Nearest person month worked: 3
Contribution to Project: Dr. Ibrahim conducts structured assessments of autism, and he is available to deliver behavior therapy for irritability. During the 3rd year of the study, he worked with Dr. Sukhodolsky and the study team to assure completeness all phenotyping assessments and he also carrying study therapy cases and participates in training new therapists. He also participates in weekly clinical supervision meetings.

Name: **Carla Kalvin, Ph.D.**
Project Role: Clinical psychologist
Researcher Identifier (ORCID ID): 0000-0002-5775-0131
Nearest person month worked: 3
Contribution to Project: Dr. Kalvin conducts structured assessments of psychiatric disorders that may co-occur with autism, and she delivers study interventions. She worked closely with Dr. Sukhodolsky to assure fidelity of treatment implementation and she also participates in weekly supervision meetings.

Name: **Joshua Snyder, M.A.**
Project Role: Behavior therapist
Researcher Identifier (ORCID ID): 0000-0001-7054-5733
Nearest person month worked: 1
Contribution to Project: Mr. Snyder has been trained to deliver study interventions during the second year of the study in accordance with the treatment manuals and during the third year he has provide behavior therapy to study participants. He also participates in weekly supervision meetings and in the weekly research meetings of the study team.

Name: **Jordan Lindy, M.A.**
Project Role: Behavior therapist
Researcher Identifier (ORCID ID): 0000-0001-5335-1208
Nearest person month worked: 1
Contribution to Project: Ms. Lindy has been trained to deliver study interventions during this year of the study in accordance with the treatment manuals and she will be able to provide behavior therapy to study participants. She also participates in weekly supervision meetings and in the weekly research meetings of the study team.

Name: **Heidi Grantz, M.S.W.**
Project Role: Independent evaluator
Researcher Identifier (ORCID ID): 0000-0002-5401-792X
Nearest person month worked: 1
Contribution to Project: Mrs. Grantz conducts structured diagnostic interviews at baseline and administers clinical outcome measures including at all assessment points. She also participates in the weekly meetings of the study team.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Dr. Fred Volkmar has retired from the Yale Child Study Center as of July 2023 and he will not longer require salary support. However, Dr. Volkmar will be professor emeritus at Yale and he will be available for

consultation to Denis Sukhodolsky and the study team on as needed basis.

What other organizations were involved as partners?

Nothing to report

8. Special Reporting Requirements

N/A

9. Appendices

None