

**Teaching Academic Success Skills to Students with Autism Spectrum Disorders in the
Clinical Setting**

Study Protocol and Statistical Analysis Plan

Clinical Trials.gov Identifier: NCT03606343

September 22, 2020

STUDY PROTOCOL

PURPOSE OF STUDY:

The goal of the study is to develop an academic EF intervention, *Achieving/Academic Independence in Middle School (AIMS)*, for high functioning (i.e., IQ score ≥ 80) middle-school youth with ASD and EF deficits. The primary aim is to: Examine the feasibility and acceptability of AIMS in a series of open trials (n=21) including the feasibility of: 1) implementing the measurement protocol, 2) operationalizing intervention delivery, 3) assessing both trained and untrained areas of functioning, 4) assessing whether improvements in academic EF skills (*proposed mechanism of treatment*) are related to functional educational outcomes (e.g., homework behaviors, grades), and 5) exploring the data for potential treatment moderators (e.g., gender, severity). It is hypothesized that AIMS will be feasible, acceptable (attendance, satisfaction), and will result in improved academic EF skills associated with reduced academic impairment and homework problems.

STUDY DESIGN:

Open Trial: To document proof of concept and gather sufficient preliminary data for a future RCT, 3 cohorts of youth with ASD (n=21) will be recruited (three groups will be recruited to participate in the group intervention; the maximum group size for this intervention is 7 based on the level of individualized attention needed during the intervention). A research assistant will observe all sessions and complete treatment fidelity checklists to monitor adherence. Sessions will also be videotaped for later use (e.g., training, fidelity coding). The primary teacher will complete organization and time management checklists weekly. We do not anticipate making major changes to the intervention during the open trials; however, as needed the intervention manual may be refined to be clearer. Parent(s) and their teen will attend 7 intervention sessions offered 1 week apart at CCHMC. Session content will include psychoeducation about the academic EFs in ASD and will be taught strategies and skills targeting these deficits, including using a behavioral contract (i.e., Agreement), organization skills (e.g., homework system, binder organization, etc.), time management skills (e.g., planner), problem solving skills, and study skills (e.g., flash cards). We will also be doing midweek check-ins with parents during the intervention to increase accountability and coach parents as needed.

Post Assessment and Exit Interviews: The primary measures collected will be treatment fidelity and academic EF skills acquisition, although other measures will be collected to pilot these measures and methods for collection and to gather information about whether they capture gains made by families. Parents and youth with ASD will also be surveyed regarding their experience of the intervention and whether they understood intervention materials in exit interviews.

Consultation with Experts: A webinar will be scheduled to process the information obtained during the open trial, including the feedback from the parents, and youth obtained in the exit interviews, the fidelity ratings, the utility and feasibility of the proposed measures.

Finalize Intervention Manual: A finalized draft of the manual will be developed including sections on troubleshooting, treatment rationale, strategies for specific skills, case examples, and

guidance for establishing and maintaining effective relationships with participants⁶⁸ will be incorporated. Finalized graphics and storyboards will be selected and scripts revised for the animated clips depicting important content.

Participants

Youth with ASD: The target population is high functioning middle school youth (6, 7, and 8th graders ages 10 to 14) who have an educational label of Autism (e.g., school referred) and/or meet diagnostic criteria for ASD (e.g., clinic referred). In cases where it may need to be clarified (e.g., youth attends a specialized school for ASD, or the child is in an intermediate school), we will confirm that youth transition between teachers for core academic subjects. For research purposes, the diagnosis of all youth will be confirmed using the ADOS-2. All participants with ASD will present with EF problems based on the parent or teacher rated BRIEF-2 T-Score >60 on the Planning, Organization, or Monitor subscales.

An IQ score ≥ 80 will be required in order to select a high functioning population that will be most likely to profit from the intervention and are more likely to be in the mainstreamed educational environment or be eligible for mainstreaming.

Youth in middle school (typical age range 10 to 14) attending public or private middle/junior high schools will be recruited. Youth receiving pullout special education services for the majority of the day will be excluded because services required for those individuals would exceed that which AIMS could address. Additionally, those who receive significant support in the classroom (e.g., one-on-one aide for the whole school day) may not benefit from the intervention given its focus on promoting independence and initiative; this will be verified by reviewing the IEP.

Both sexes will be represented although more males than females (4:1 ratio) are anticipated given prevalence data for ASD⁶⁹.

Parents/Caregivers of Youth with ASD: Since parents/caregivers will be critically involved in implementing and reinforcing the intervention components, their input will be invaluable. Parents will be the primary caregiver of a child with high functioning ASD, English-speaking, and be willing and able to attend the intervention sessions.

Expert Consultants: An expert panel of consultants with expertise in academic issues facing youth with ASD and with developing and implementing school-based interventions will provide feedback on the final manual.

Measures: Measures collected will include information on family background, and measures assessing eligibility, EF, academic functioning, self-determination, parent-child relationship and satisfaction. Also see Table 1.

Participant Demographics & Eligibility:

Family Demographic/Developmental History: Includes family status, parent occupation, education, medical and developmental history, school history (including special education placements) completed by parents.

*Autism Diagnostic Observation Schedule, 2nd Edition (ADOS-2)*⁷⁰ is the “gold standard” clinician-administered assessment that will examine social interaction, language and communication, and restricted and repetitive behaviors and interests. All youth will be administered Module 3 of the ADOS-2 to confirm ASD diagnosis. Note that if an ADOS-2 has

been administered within the past two years by staff at CCHMC, parents will be asked to sign a release of information form and the results from that assessment will be obtained.

*Kaufman Brief Intelligence Tests-2 (K-BIT)*⁷¹: The K-BIT is a culturally-sensitive standardized assessment that estimates verbal and non-verbal and overall intelligence. This test has good reliability and validity and will be administered to confirm that the participant has an IQ ≥ 80 . Note that if a K-BIT has been administered within the past year for other research studies at CCHMC, parents will be asked to sign a release of information form and the results from that assessment will be obtained.

Executive Functioning

*Behavior Rating Inventory of Executive Function (BRIEF)*⁷³: Parents and teachers will complete the BRIEF assessing EF behaviors in the home and school environments.

*Children’s Organizational Skills Scale (COSS)*⁷⁴: Parents, teens, and teachers will complete the COSS assessing multiple facets of a child’s organizational skills.

Academic Functioning

*Subtests of the Woodcock Johnson Tests of Achievement III (WJ)*⁷⁶: Reading Comprehension (#9,#17), Basic Writing Cluster (#7,# 16), Math Reasoning Cluster (#10, #18), and the Academic Knowledge subtest (# 19) will be administered to assess academic achievement in student participants.

*Homework Problems Checklist (HPC)*⁷⁷: The HPC is a parent-report instrument that is commonly used as a screening tool for and outcome measure of homework problems.

*Classroom Performance Survey (CPS)*⁷⁸: The CPS, completed by teachers, is a measure of academic impairment specifically designed for secondary school youth. A shorter variant of this scale will be completed by teachers on a weekly basis while the child is attending the intervention.

*Academic Performance Rating Scale (APRS)*⁷⁹: The APRS is a 19-item scale that is completed by the teacher that measures how well the child is performing academically in the classroom.

Parent-Youth Relationship

*Parenting Relationship Questionnaire (PRQ)*⁸⁰. The PRQ is a parent-report instrument reporting on how parents feel about their children and the task of parenting. Subscales include Communication, Involvement, Satisfaction with School, Parenting Confidence, Relational Frustration, Attachment, and Discipline Practices. Lower T-scores indicate greater severity of relationship problems. This measure is included to assess whether parents report improvements in communication, satisfaction with school, increased confidence, and decreased frustration.

Table 1. Measures	Rater	Time	Eligibility	Pre	AIMS	Post	Domain
Autism Diagnostic Observation Schedule	Y	60	X				
Kaufman Brief Intelligence Test – Second Ed. (KBIT-2)	Y	20	X				
Behavior Rating Inventory of Executive Function Second Edition (BRIEF-2)	P, T	10	X			X	EF
Children’s Organizational Skills Scale (COSS)	P, T, Y	10		X		X	EF
Woodcock Johnson (WJ-III) Achievement Subtests	Y	30		X		X	A
Homework Problems Checklist (HPC)	P	5		X		X	A
Classroom Performance Survey (CPS)	T	10		X		X	A
Academic Performance Rating System (APRS)	T	10		X		X	A

Parenting Relationship Questionnaire (PRQ)	P	10-15		X		X	PY
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Y = Youth, P = Parent, T = Teacher, EF = academic executive functioning skill, A = academic outcome, PY=Parent-Youth relationship, I = Independence/Initiative, S = Satisfaction

Recruitment and Informed Consent

The investigative team has considerable experiencing with recruiting and retaining youth with ASD in intervention studies and recruitment difficulties are not anticipated. The team has well-established contacts with public and private school systems in Cincinnati and surrounding areas, and notices will be placed in schools to alert teachers and parents about this research opportunity. Clinicians and physicians at the Kelly O’Leary Center (TKOC) for Autism, the Division of Developmental Behavioral Pediatrics, and the Division of Psychiatry at Cincinnati Children’s Hospital Medical Center’s (CCHMC) will also be notified about this opportunity. Participants with ASD will also be recruited from local schools, including those specializing in ASD, as well as from the TKOC.

At TKOC, students will be identified through a variety of resources including (1) an existing database of children and adolescents who were previously assessed and diagnosed with an ASD at TKOC; (2) Dr. Duncan’s existing research database of 150 youth with ASD who have participated in her previous studies; (3) an existing research database of ~60 youth with ASD who have participated in studies through the CCHMC Psychiatry Department; (4) treatment referrals from clinicians at TKOC and community providers. Currently, there are 178 youth between the ages of 10 to 14 years, which is the typical age of middle schoolers, who were evaluated or received treatment at TKOC in 2017 and could be recruited for the current research study; additionally, there are 94 individuals in this age range on the waitlist for services at TKOC that could also be approached. Families may be sent a letter indicating that they were identified because of having been seen previously at TKOC along with a “do not contact” postcard. Families not returning the postcards will be called by research staff to share more about the study and invite participation.

At schools, Student Services Directors, Special Educators, school mental health professionals, and/or teachers will be approached to identify high functioning middle school students with ASD who might be interested in participating. These individuals will be provided with a recruitment letter and flyer to distribute to parents of these youth. Students with an Individualized Education Program (IEP) that includes items related to EF (e.g., organization challenges), or whom teachers and/or school MHPs consider as having significant challenges in these domains will be of particular interest.

Participants may be recruited using IRB-approved materials including advertising and/or print, electronic, social and digital media, news/broadcast, face-to-face marketing and flyers at Cincinnati Children’s and in the community. Some of these recruitment materials will direct potential participants to a REDCap e-screener page where potential participants will be directed to provide contact information so that study staff may contact the participants to inform them about the study.

An initial eligibility screen will be conducted by telephone which will include asking parents to give verbal permission for us to contact the teacher to complete the BRIEF-2. Eligible families will be invited to an in-person screening visit at CCHMC. At the in person screening visit, the consent form and assent form, which are written in a language that is understandable to parents and teens, will be reviewed in detail. The consent form will also clarify that their data will be shared with other researchers via the National Database for Autism Research (NDAR) without exposing personally identifiable information. Upon conclusion of the review, the project

coordinator will ask if the parent and child are still interested in the study and if they are willing to sign the consent/assent forms— one will be provided for the family to keep for their records and one to sign for the study. We may consent the families electronically and send them an electronic copy of the consent/assent forms via REDCap. After signing the consent/assent forms, the baseline assessment battery will commence. This will include the a) ADOS-2⁷⁰ to assess ASD symptoms, the Stanford-Binet 5th Edition⁷² to confirm IQ, and the BRIEF-2 to confirm EF difficulties. For those youth who meet criteria, additional measures will be administered either at the screening visit or at a second visit depending on the families' wishes and fatigue level, assessing the outcomes of interest (e.g., Homework Problems Checklist, academic testing). We will also be asking the parents to bring a copy of their child's school IEP in order to determine if they fit criteria of being in a mainstream classroom for majority of the day without too much support from school staff.

Teachers are also participants in this study as they complete ratings of academic functioning that are critical to the study aims. Thus, engaging and retaining school personnel throughout the study will be important. The PIs will provide an overview of the study to teachers and provide an opportunity to ask questions as needed. The importance of teacher participation will be emphasized as crucial to accomplishing the aims of the study. In addition, teachers will be compensated for their time and effort in completing ratings.

STATISTICAL ANALYSIS PLAN

Descriptive statistics will summarize attendance, satisfaction (AIQ), fidelity, drop-out rates, exit interview data to assess feasibility and acceptability. Within group (pre-test, post-test) mixed factorial ANCOVAs controlling for pre-test scores will test for the presence of improvements. It is hypothesized that youth with ASD will demonstrate improved academic EF skills (BRIEF-2, COSS, HPC). The primary analytic focus will be on evaluating whether the observed effect sizes across outcomes warrant continued study of AIMS as a treatment strategy. A moderate (i.e., Cohen's $d = .5$ ⁸¹) effect size for academic EF measures will be evidence of significant improvement. We will explore whether AIMS improves academic (WJ, CPS, APRS), and parent-child relationship (PRQ) outcomes between pre- and post- assessments. Correlations between changes in academic EF skills and changes in the other outcomes measures will also be computed to explore whether changes in academic EF skills are related to functional academic outcomes, as these are the primary target and proposed mechanism of treatment.

Exploratory Analyses: We will also explore potential moderators such as sex, IQ, ASD and EF severity, and socioeconomic status qualitatively and with non-parametric statistics given the lack of power.

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