

**AWARD NUMBER:** W81XWH-18-1-0790

**TITLE:** Comparative Effectiveness of EIBI and Adaptive ABA for Children with Autism

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**CONTRACTING ORGANIZATION:** University of Rochester  
Rochester, NY 14642

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**14. ABSTRACT**

**Background:** Approximately 15,000 children with autism spectrum disorder (ASD) in military families currently receive applied behavior analysis (ABA) interventions through TRICARE insurance. This includes early intensive behavioral intervention (EIBI), which involves 20 or more hours per week of individualized instruction based on ABA and is often considered the standard of care for toddlers and preschoolers with ASD. Research indicates that EIBI accelerates development of cognitive and adaptive skills in many children with ASD. However, the evidence base has important gaps, notably a dearth of randomized controlled trials (RCTs), limited data on whether EIBI reduces ASD symptoms, and few studies on outcomes of EIBI in community settings such as private agencies where most children with ASD receive services. In addition, EIBI is expensive and requires a substantial commitment of time and effort from children and families.

More recently, research has found that less intensive, time limited ABA interventions can effectively target specific core and associated features of ASD. With these latest data, we assert that an individualized approach to adapting and combining targeted interventions could be at least as effective as EIBI, yet substantially reduce expenditures of time and resources. We call this approach adaptive, modular ABA (AM-ABA).

**Objectives/Hypotheses:** We will compare EIBI as usual, provided for approximately 20 hours per week, and AM-ABA, provided for up to 10 hours per week, in a 24-week RCT of 130 children with ASD, under age 5 years, in military families. We hypothesize that, at the end of intervention, AM-ABA will be no less effective than EIBI as usual, or only slightly so, on the primary outcome measure (a standardized measure of adaptive skills). We also hypothesize that, at follow-ups conducted 24 weeks after intervention and when children are 5 years old, AM-ABA will be superior to EIBI on primary and secondary child outcomes (tests of cognitive and language function, parent- and provider-rated ASD symptoms and adaptive skills) and on parent outcomes (parent stress and sense of competence).

**Specific Aims:** Our primary aim is to compare EIBI and AM-ABA on key child and parent outcomes after 24 weeks of intervention, at a 24 week follow-up, and at age 5 years. We also explore whether child functioning and family environment moderate the effects of intervention, and we examine potential facilitators and barriers to future implementation of AM-ABA (e.g., parent and provider buy-in, fidelity of intervention, cost).

**Design:** We will randomize 130 children with ASD to receive 24 weeks of either 1) EIBI as usual for approximately 20 hours per week or 2) our adaptive intervention (MABA), in which children start with intervention focused on social communication 5 hours per week for 4 weeks and then, depending on clinical evaluation of their response, either continue in this intervention or receive augmented intervention for 20 weeks, up to 10 hours per week. Both EIBI and MABA use a tiered delivery system in which trained paraprofessionals provide most of the direct intervention under the supervision of licensed or credentialed professionals. Participants will be recruited from 5 sites that have longstanding relationships with nearby military bases: Vanderbilt University, University of Florida, Nationwide Children’s Hospital, May Institute, and Trumpet Behavioral Health. Experts on military families will advise the study team on implementation of the study. Child outcome measures assess 1) adaptive skills, 2) ASD symptoms, 3) cognition, and 4) language. Parent outcome measures assess caregiver stress and sense of competence. Linear mixed models (LMMs) will be used to contrast the two interventions in terms of change in outcomes on each measure from baseline through the primary endpoint (end of intervention at Week 24) and at follow-up evaluations. To explore moderators, we will augment the LMMs with standard moderated (i.e., covariate-by-treatment) regression analyses. To examine implementation, we will compare EIBI and AM-ABA on implementation variables such as buy-in, fidelity, and cost.

**Impact/Military Relevance:** By design, MABA intervention imposes substantially less burden on children with ASD and families than does EIBI (from 5 to no more than 10 hours of intervention per week, compared to the 20 hours per week with EIBI). Nonetheless, we predict that 1) MABA will be no less effective than EIBI as usual, or only slightly so, in terms of changing adaptive behavior, and 2) MABA will be superior to EIBI on other outcomes because it is targeted, composed of empirically supported intervention strategies, and tailored to the evolving status of the child (i.e., intervention is personalized). Such an outcome would have important implications for families of children with ASD and policy-makers, and it would be particularly relevant to the military because all participating children will be TRICARE beneficiaries.

**15. SUBJECT TERMS**

**Autism, autism spectrum disorder, early intensive behavior intervention (EIBI), applied behavior analysis (ABA), parent training**

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## 1. INTRODUCTION:

**Background:** Approximately 15,000 children with autism spectrum disorder (ASD) in military families currently receive applied behavior analysis (ABA) interventions through TRICARE insurance. This includes early intensive behavioral intervention (EIBI), which typically involves 20 or more hours per week of individualized instruction based on ABA and is often considered the standard of care for toddlers and preschoolers with ASD. Research indicates that EIBI accelerates development of cognitive and adaptive skills in many children with ASD. However, the evidence base has important gaps, notably a dearth of randomized controlled trials (RCTs), limited data on whether EIBI reduces core ASD symptoms in social communication, and few studies on outcomes of EIBI in community settings such as private agencies where most children with ASD receive services. In addition, EIBI is expensive and requires a substantial commitment of time and effort from children and families. More recently, research has found that less intensive, time limited ABA interventions can effectively target specific core and associated features of ASD. With these latest data, we assert that an individualized approach to adapting and combining targeted interventions could be at least as effective as EIBI, yet substantially reduce expenditures of time and resources. We call this approach adaptive, modular ABA (MABA).

**Objectives/Hypotheses:** We will compare EIBI as usual, provided for 20 hours per week, and MABA, provided for up to 10 hours per week, in a 24-week RCT of 132 children with ASD, under age 5 years, in military families. We hypothesize that, at the end of intervention, MABA will be no less effective than EIBI as usual, or only slightly so, on the primary outcome measure (a standardized measure of adaptive skills). We also hypothesize that, at follow-ups conducted 24 weeks after intervention and when children are 5 years old, MABA will be superior to EIBI on primary and secondary child outcomes (tests of cognitive and language function, parent- and provider-rated ASD symptoms and adaptive skills) and on parent outcomes (parent stress and sense of competence).

**Specific Aims:** Our primary aim is to compare EIBI and MABA on key child and parent outcomes after 24 weeks of intervention, at a 24-week follow-up, and at age 5 years. We also explore whether child functioning and family environment moderate the effects of intervention, and we examine potential facilitators and barriers to future implementation of MABA (e.g., parent and provider buy-in, fidelity of intervention, cost).

**Design:** We will randomize 130 children with ASD to receive 24 weeks of either 1) EIBI as usual for 20+ hours per week or 2) our adaptive intervention (MABA), in which children start with intervention focused on social communication 5 hours per week for 4 weeks and then, depending on clinical evaluation of their response, either continue in this intervention or receive augmented intervention for 20 weeks, up to 10 hours per week. Both EIBI and MABA use a tiered delivery system in which trained paraprofessionals provide most of the direct intervention under the supervision of licensed or credentialed professionals. Participants will be recruited from 4 sites: Vanderbilt University Medical Center, Cleveland Clinic, Nationwide Children's Hospital, and May Institute. Child outcome measures assess 1) adaptive skills, 2) ASD symptoms, 3) cognition, and 4) language. Parent outcome measures assess caregiver stress and sense of competence. Linear mixed models (LMMs) will be used to contrast the two interventions in terms of change in outcomes on each measure from baseline through the primary endpoint (end of intervention at Week 24) and at follow-up evaluations. To explore moderators, we will augment the LMMs with standard moderated (i.e., covariate-by-treatment) regression analyses. To examine implementation, we will compare EIBI and MABA on implementation variables such as buy-in, fidelity, and cost.

**Impact/Military Relevance:** By design, MABA intervention imposes substantially less burden on children with ASD and families than does EIBI (from 5 to no more than 10 hours of intervention per week, compared to the 20 hours per week with EIBI) but calls for more targeted intervention including training. We predict that 1) MABA will be no less effective than EIBI as usual in increasing adaptive behavior, and 2) MABA will be superior to EIBI on other outcomes because it is targeted, composed of empirically supported intervention strategies, and tailored to the evolving status of the child (i.e., intervention is personalized). Such an outcome would have important implications for families of children with ASD and policymakers, and it would be particularly relevant to the military because all participating children will be TRICARE beneficiaries.

## 2. KEYWORDS:

autism, autism spectrum disorder, early intensive behavior intervention, EIBI, modular applied behavior analysis, MABA, parent training, social communication, disruptive behaviors, repetitive behaviors feeding, sleep, elopement, toileting

## 3. ACCOMPLISHMENTS:

### What were the major goals of the project?

Major goals relevant for this second year of this project include:

1. Enrollment of participants
2. Data management and data collection
3. Ongoing recruitment
4. Randomization and retention of participants
5. Monitoring of treatment fidelity
6. Maintain regulatory requirements.

These are ongoing at this phase of the project.

### What was accomplished under these goals?

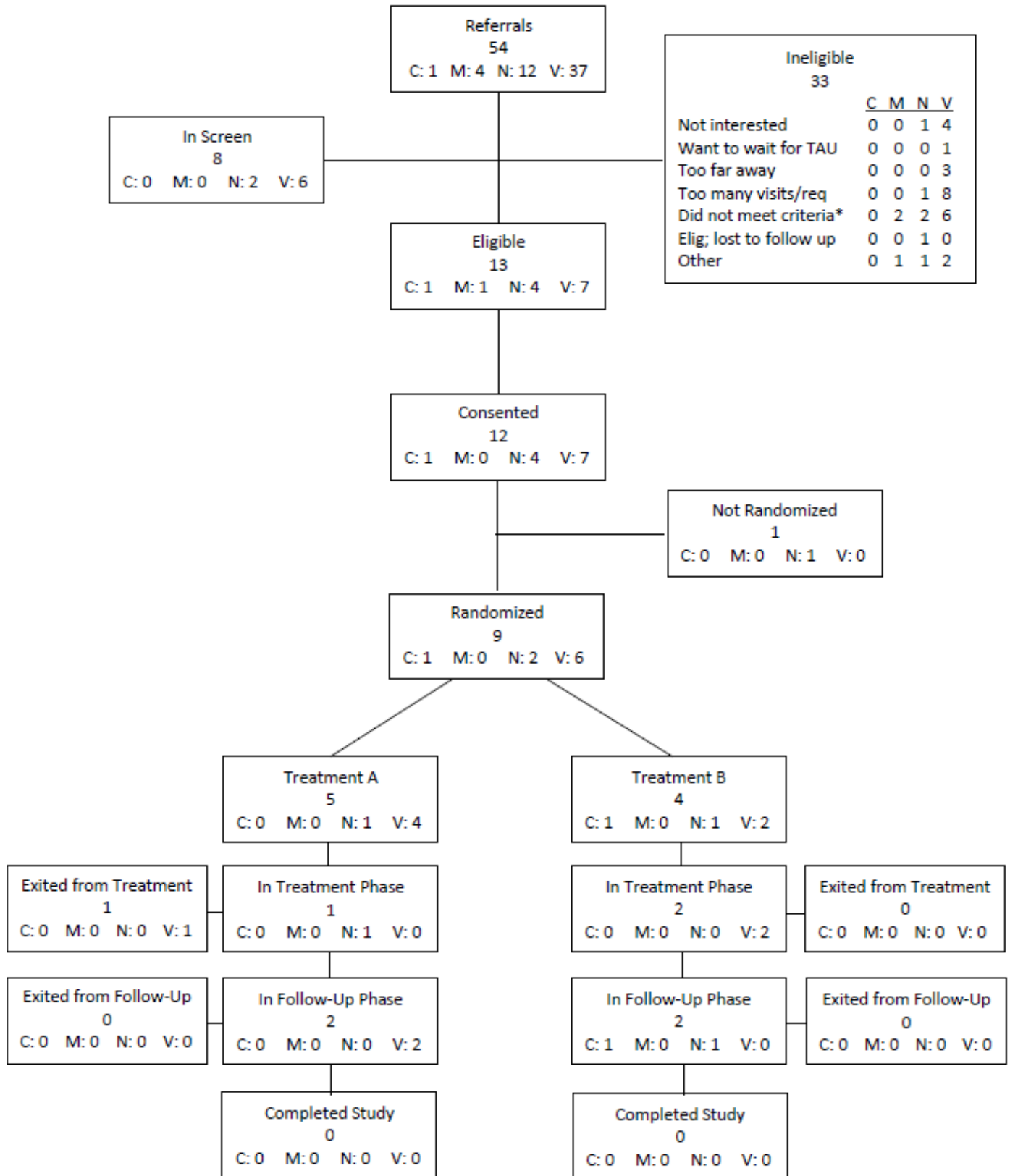
During this second year, tasks centered around recruitment, enrollment, delivery of the treatments, data collection and data entry. These tasks along with ongoing maintenance of regulatory requirements including IRB approvals were also goals for year 02. The study team has spoken with 54 parents who have indicated interest (through 09/29/2020). We have completed screens on 46 participants, completed full baseline assessment of 9 participants and randomized 9 participants. The consort chart below provides details of our recruitment, enrollment, and study completion as of closing of year 02. Data entry is up to date.

We have had two DSMB meeting during this 2<sup>nd</sup> year (April and October, 2020).

Initial and maintenance staff training continues to be ongoing since the project was initiated. These include ongoing training in the multifaceted MABA intervention and independent evaluator training. Case panels are further held 2-3 times per month to establish and maintain a common culture in the implementation of both treatment arms.

CONSORT Chart

Data through 09/29/2020



Baseline Characteristics (as of 9/29/2020)

		All N = 9	
		<u>N</u>	<u>%</u>
<b>Gender</b>			
Male		8	88.89
Female		1	11.11
<b>Age (months)</b>	<i>(Mean, SD)</i>	40.22	10.58
<b>Race</b>			
White		7	77.78
Non-white		2	22.22
Unknown		0	0.00
<b>Hispanic</b>		2	25.00
<b>Child activity (School Program)</b>			
Full-time GenEd		1	12.50
GenEd with SpEd services		1	12.50
SpEd with minimal incl.		1	12.50
Full-time SpEd		0	0.00
Specialized school		1	12.50
Home School		0	0.00
Other		1	0.00
Not in school		4	50.00
<b>Mother's education</b>			
Eighth grade or less		0	0.00
Some high school		0	0.00
High school grad		1	11.11
Some college		4	44.44
College graduate		2	22.22
Advanced degree		2	22.22
Not in household		0	0.00
<b>Father's education</b>			
Eighth grade or less		0	0.00
Some high school		0	0.00
High school grad		3	33.33
Some college		1	11.11
College graduate		4	44.44
Advanced degree		1	11.11
Not in household		0	0.00
<b>Household income</b>			
Less than \$20,000		0	0.00
\$20,001 - \$40,000		0	0.00
\$40,001 - \$60,000		3	33.33
\$60,001 - \$80,000		1	11.11
\$80,001 - \$100,000		4	44.44
More than \$100,000		1	11.11
<b>Baseline Scores</b>			
VABS-3	<i>(Mean, SD)</i>	65.89	12.33
Mullen	<i>(Mean, SD)</i>	60.50	13.47
Stanford Binet	<i>(Mean, SD)</i>	82.00	--
PLS-5	<i>(Mean, SD)</i>	78.00	26.95

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

- 1) Training of Board-Certified Behavior Analyst staff and Registered Behavior Technician staff as noted in MABA and EIBI treatment fidelity procedures.
- 2) Training of assessors (e.g. psychologists, psychometricians, and research assistants) in use of multi-method assessments to evaluate the severity of ASD symptoms and response to intervention.
- 3) No training as of date for those outside of the research teams.

**How were the results disseminated to communities of interest?**

Nothing to report.

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

1. Increase recruitment at Vanderbilt site to capture families from Fort Campbell by offering home-based delivery in addition to center-based services.
2. Increase recruitment at May Institute by opening up 1-2 research dedicated sites to provide home-based services.
3. Resume collaborative relationship between Wright-Patterson base and Nationwide Children's to improve recruitment with a return to in-person service delivery.
4. Cleveland Clinic will continue close surveillance of any TRICARE families in the Northeast region of Ohio.
5. Utilization of ResearchMatch.org as an additional recruitment source.
6. Budgets are being adjusted to account from differences in anticipated recruitment capacity.

**4. IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report.

**What was the impact on other disciplines?**

Nothing to report.

**What was the impact on technology transfer?**

Nothing to report.

**What was the impact on society beyond science and technology?**

Nothing to report.

**5. CHANGES/PROBLEMS:**

**Changes in approach and reasons for change**

Secondary to the COVID-19 pandemic, changes have been made to the assessments. Assessments will be conducted virtually as required as needed, with the goal to collect in-person whenever possible.

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

The COVID-19 pandemic resulted in all recruiting sites to be closed for varying time intervals since March 2020. While all sites have resumed services during May, June or July, capacity remains limited due to adherence to the required significant safety measures. Moreover, families have been reluctant to restart services or to be randomized to 20+ hours per week due to concern about COVID-19. These issues are compounded by the narrow inclusion criteria of recruiting only families accessing TRICARE for ABA services along with the barriers of the Humana / TRICARE system (e.g., delays in credentialing of personnel, delays in approval of services). At this time, we will closely monitor recruitment, screening and enrollment to determine barriers and identify strategies to resolve. This is a regular agenda item for our weekly steering committee teleconferences.

**Changes that had a significant impact on expenditures**

Expenditures were less than budgeted due to low recruitment. Budgets are being reallocated to reflect potential recruitment capacity.

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

Secondary to COVID-19 pandemic, CDC guidelines along with other institutional guidelines, safety practices including use of PPE, social distancing and limiting in-person visits when possible were instituted.

**6. PRODUCTS:**

- **Publications, conference papers, and presentations**

**Journal publications**

None to date.

**Books or other non-periodical, one-time publications.**

None to date.

**Other publications, conference papers and presentations.**

None to date.

- **Website(s) or other Internet site(s)**

Nothing to report.

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

None to date.

- **Other Products**

Nothing to report.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

#### **Cleveland Clinic**

Name: Cynthia R. Johnson, PhD

Project Role: Principal Investigator

Research Identifier: eRAcommons – Johnsoncr; ORCID iD 0000-0002-1395-6779

Nearest person month worked: 3.0

Contribution to Project: Dr. Johnson provides oversight and supervision of all study personnel at her site. In addition to her role as an intervention site PI, she oversees all scientific aspects of the study to include intervention-related and administrative processes of the project including cross-site recruitment, standard operating procedures, and regulatory requirements (IRB), preparation of progress reports and manuscripts and she will lead the cross-site Steering Committee.

Name: Maureen Intihar, BCBA

Project Role: Behavior Analyst and Parent Trainer

Research Identifier: N/A

Nearest person month worked: 1.2

Contribution to Project: Ms. Intihar is a BCBA who oversees both treatment arms. She is also a parent trainer on the project.

Name: Destiny Kaznoch

Project Role: Project Coordinator

Research Identifier: N/A

Nearest person month worked: 6.0 (up to 07/01/2020)

Contribution to Project: Ms. Kaznoch has been key in completing regulatory requirements and is now actively recruiting and scheduling potential participants. She oversaw data entry.

Name: Leah Barto, MPH

Project Role: Project Coordinator

Research Identifier:

Nearest person month worked: 6.0 (since 7/01/2020)

Contribution to Project: Ms. Barto replaced Ms. Kaznoch as coordinator effect 07/01/2020 but was first trained by Ms. Kaznoch. She has been instrumental in recruitment efforts, screening and enrollment, assisting with regulatory requirements, and data collection / entry.

Name: Nicholas Dodd

Project Role: Registered Behavior Technician

Research Identifier: N/A

Nearest person month worked: 1.2 calendar months (up to 08/01/2020)

Contribution to Project: Mr. Dodd has been participating in training in preparation for providing the one-on-one intervention for both treatment arms.

Name: Amber Grenig

Project Role: Registered Behavior Technician

Research Identifier: N/A

Nearest person month worked: 1.2 calendar months

Contribution to Project: Ms. Grenig has been participating in preparation for providing the one-on-one intervention for both treatment arms.

*Continued below...*

Name: Tracy Masterson, PhD  
Project Role: Independent Evaluator  
Research Identifier: N/A  
Nearest person month worked: 2.4  
Contribution to Project: Dr. Masterson is a primary independent evaluator for this project. She serves as IE for Cleveland and May.

Name: Rebecca Rothstein, MA, BCBA  
Project Role: Independent Evaluator  
Research Identifier: N/A  
Nearest person month worked: 1.2 (in kind)  
Contribution to Project: Ms. Rothstein is a back-up independent evaluator for this project.

### **May Institute**

Name: Cynthia Anderson, PhD  
Project Role: Principal Investigator  
Research Identifier: ORCID iD: 0000-0002-0844-6184  
Nearest person month worked: 2.4  
Contribution to Project: Dr. Anderson provides oversight and supervision of all aspects of this project, assists in the training of study personnel and interventions, responsible for development and training for Restricted/Repetitive Behavior modules, and monitors treatment fidelity across the network, in addition to her site PI roles.

Name: Ryan Martin, PhD  
Role: Study Coordinator  
Research Identifier: ORCID iD 0000-0002-5999-4471  
Nearest person month worked: 9.6  
Contribution to Project: Assist PI with implementation of the project, including development and training for Restricted/Repetitive Behavior modules; recruitment and screening of study participants; participant ascertainment; data entry and data management; reports for DOD and IRBs.

Name: Alice Shillingsburg, PhD  
Project Role: Investigator  
Research Identifier: ORCID iD 0000-0001-6537-2532  
Nearest person month worked: 2.4 (up to 07/13/2020)  
Contribution to Project: Oversaw initial development, training, and implementation of the SCEI intervention.

Name: Christina Hardy, BCBA-D  
Project Role: BCBA  
Research Identifier: N/A  
Nearest person month worked: N/A  
Contribution to Project: Program director of a May Institute implementation site; was to serve as a supervising BCBA for participating children.

Name: Sydney Ball, BCBA  
Project Role: BCBA  
Research Identifier: N/A  
Nearest person month worked: N/A  
Contribution to Project: Will provide behavioral services for enrolled participants.

Name: Sarah Frampton, BCBA  
Project Role: Intervention Development & Training  
Research Identifier: ORCID iD 0000-0002-9279-7998  
Nearest person month worked: N/A  
Contribution to Project: Assisted Dr. Shillingsburg with developing SCEI intervention materials and training study staff on SCEI procedures.

Name: Erin Mahaffey, NCSP  
Project Role: Independent Evaluator  
Research Identifier: N/A  
Nearest person month worked: N/A (up to 07/22/2020)  
Contribution to Project: Was to conduct evaluations of study variables, including cognitive and adaptive functioning and autism symptoms; completing all initial training as needed through the study and participation in cross-site evaluator videoconferences and planning meetings, as appropriate for blinded independent evaluators.

Name: Samantha Anderson, BCBA  
Project Role: Independent Evaluator  
Research Identifier: N/A  
Nearest person month worked: N/A (up to 07/22/2020)  
Contribution to Project: Was to conduct evaluations of study variables, including cognitive and adaptive functioning and autism symptoms; completing all initial training as needed through the study and participation in cross-site evaluator videoconferences and planning meetings, as appropriate for blinded independent evaluators.

Name: Erin Cooper  
Project Role: Independent Evaluator  
Research Identifier: N/A  
Nearest person month worked: N/A (up to 07/22/2020)  
Contribution to Project: Was to conduct evaluations of study variables, including cognitive and adaptive functioning and autism symptoms; completing all initial training as needed through the study and participation in cross-site evaluator videoconferences and planning meetings, as appropriate for blinded independent evaluators.

Name: Helayna Banks  
Project Role: Independent Evaluator  
Research Identifier: N/A  
Nearest person month worked: N/A (up to 07/22/2020)  
Contribution to Project: Conducting evaluations of study variables, including cognitive and adaptive functioning and autism symptoms; completing all initial training as needed through the study and participation in cross-site evaluator videoconferences and planning meetings, as appropriate for blinded independent evaluators.

Name: Jaime Crowley  
Project Role: Postdoctoral Fellow  
Research Identifier: N/A  
Nearest person month worked: 7.2  
Contribution to Project: Assist PI and coordinator with implementation of the project, including development and training for Restricted/Repetitive Behavior modules; recruitment and screening of study participants; participant ascertainment; data entry and data management; reports for DOD and IRBs.

Name: John Tolson, BCBA  
Project Role: BCBA  
Research Identifier: N/A  
Nearest person month worked: N/A  
Contribution to Project: Will provide behavioral services for enrolled participants.

Name: Erin "Katy" Palmer, BCBA  
Project Role: BCBA  
Research Identifier: N/A  
Nearest person month worked: N/A  
Contribution to Project: Will provide behavioral services for enrolled participants.

Sara Lamont, BCBA  
Project Role: BCBA  
Research Identifier: N/A  
Nearest person month worked: N/A  
Contribution to Project: Will provide behavioral services for enrolled participants.

Name: Caroline Mueller, BCBA  
Project Role: BCBA  
Research Identifier: N/A  
Nearest person month worked: N/A  
Contribution to Project: Will provide behavioral services for enrolled participants.

Name: James Rannenburg, BCBA  
Project Role: BCBA  
Research Identifier: N/A  
Nearest person month worked: N/A  
Contribution to Project: Will provide behavioral services for enrolled participants

Name: Kathleen Salzman  
Project Role: Site coordinator  
Research Identifier: N/A  
Nearest person month worked: N/A  
Contribution to Project: Will provide assistance and logistical support for research coordination at the implementation site.

### **Nationwide Children's Hospital**

Name: Eric Butter, Ph. D.  
Role: Site Principal Investigator  
Research Identifier: ORCID iD 0000-0002-1924-9055  
Nearest person month worked: 0.05  
Contribution to Project: Oversees all aspects of the project; leads cross-site assessment call, attends intervention, data coordinating, and steering committee calls; development and training for assessments.

Name: Jacqueline Wynn, Ph. D., BCBA-D

Role: Co-Investigator, Site supervisor and administrative lead for clinical services supporting study treatments.

Research Identifier: N/A

Nearest person month worked: 0.05

Contribution to Project: Assist with development of clinical models; oversee implementation of clinical interventions (both treatment arms) and clinical personnel; attends cross-site intervention calls.

Name: Ashley Showalter, PhD

Role: Intervention supervisor

Research Identifier: N/A

Nearest person month worked: 0.05

Contribution to Project: Oversaw both treatment arms; integration and interpretation of data; attends cross-site intervention calls. Oversees intake process for participants into the Center for Autism Spectrum Disorders as clients.

Name: Christin McDonald-Fix, Ph.D., BCBA, COBA

Role: Co-Investigator, Clinical Supervisor for study treatments

Research Identifier: ORCID iD 0000-0002-0402-3440

Nearest person month worked: 0.0

Contribution to Project: Oversee both treatment arms; integration and interpretation of data; attends cross-site intervention calls; was on leave during part of this year.

Name: Megan Norris, Ph. D.

Role: Co-Investigator

Research Identifier: N/A

Nearest person month worked: 0.25

Contribution to Project: Oversees assessment and personnel; integration and interpretation of data; attends cross-site assessment calls.

Name: Kevin Stephenson, Ph. D.

Role: Masked Independent Evaluator

Research Identifier: ORCID iD 0000-0002-5196-9407

Nearest person month worked: 0.20

Contribution to Project: Conducting evaluations of study variables, including cognitive and adaptive functioning and autism symptoms; attends cross-site assessment calls.

Name: Erin Given

Role: Study Coordinator

Research Identifier: N/A

Nearest person month worked: 0.95

Contribution to project: Trained on assessments required for the study; attended bi-weekly site calls. Assists with recruitment.

Name: Sara Eldred, B.A.

Role: Study Coordinator

Research Identifier: N/A

Nearest person month worked: 0.0

Contribution to project: Attended study calls; entered participant data into REDCap. Trained on assessments required for the study and on protocols and procedures. Assists with recruitment.

Name: Teresa Ibanez, B.S.

Role: Study Coordinator

Research Identifier: N/A

Nearest person month worked: 0.50

Contribution to Project: Trained on assessments required for the study; Attends all calls; contact point between coordinating site and Nationwide Children's; Oversees recruitment and data collection. Ensures protocol is followed.

Name: Nancy Long

Role: Study Coordinator

Research Identifier: N/A

Nearest person month worked: 0.05

Contribution to project: Assists with recruitment

Name: Nicole Cacciato

Role: Study Coordinator

Research Identifier: N/A

Nearest person month worked: 0.40

Contribution to project: Assists with recruitment, attends study calls, and scheduling study appointments.

Name: Lauren Stahler (Hengstler), MA, BCBA, COBA

Role: BCBA

Research Identifier: N/A

Nearest person month worker: 0.10

Contribution to project: Oversees the RBTs for both arms, completes tailoring, delivers parent training; attended and contributed to DOD start-up meeting, and participated in pilot case. Attends and contributes to weekly MABA calls.

Name: Sarah Canada, M.Ed, BCBA, COBA

Role: BCBA

Research Identifier: N/A

Nearest person month worker: 0.0

Contribution to project: Trained in overseeing the RBTs for both arms, completing tailoring, and delivering parent training. Attends and contributes to weekly MABA calls.

Name: Sarah Leiss, M.Ed., BCBA, COBA

Role: BCBA

Research Identifier: N/A

Nearest person month worker: 0.0

Contribution to project: Trained in overseeing the RBTs for both arms, completing tailoring, and delivering parent training. Attends and contributes to weekly MABA calls.

Name: Chase Dieckhoner, B.A.

Role: RBT

Research Identifier: N/A

Nearest person month worked: 0.0

Contribution to Project: Provides treatment to study participant.

Name: Gabe Cruz, B.A.  
Role: RBT  
Research Identifier: N/A  
Nearest person month worked: 0.0  
Contribution to Project: Provides treatment to study participant.

Name: Jacqueline Brito  
Role: RBT  
Research Identifier: N/A  
Nearest person month worked: 0.0  
Contribution to Project: Participated in pilot case. On standby to provide treatment.

Name: Jenna Sullivan, B.A.  
Role: RBT  
Research Identifier: N/A  
Nearest person month worked: 0.0  
Contribution to Project: Trained for SCEI treatment. On standby to provide treatment.

Name: Sarah McGurk, B.A.  
Role: RBT  
Research Identifier: N/A  
Nearest person month worked: 0.0  
Contribution to Project: Trained for SCEI treatment. On standby to provide treatment.

Name: Taylor Treace, B.A.  
Role: RBT  
Research Identifier: N/A  
Nearest person month worked: 0.0  
Contribution to Project: On standby to provide treatment.

Name: Jeff Brauning  
Role: Study Coordinator  
Research Identifier: N/A  
Nearest person month worked: 0.90 (up to 03/06/2020)  
Contribution to project: Ensured compliance with regulations; planning for monitoring site data collection and adherence to regulatory requirements; attends cross-site assessment, intervention, data coordinating, and steering committee calls. No longer part of the study; ended his employment during this reporting period.

Name: La'Daisy Turner, B.A.  
Role: RBT  
Research Identifier: N/A  
Nearest person month worked: 0.0  
Contribution to project: Provided treatment to participants in both arms. No longer in the study.

Name: Tateyana Caliman  
Role: RBT  
Research Identifier: N/A  
Nearest person month worked: 0.0  
Contribution to Project: Participated in pilot case. No longer part of the study.

### **Vanderbilt University Medical Center**

Name: Zachary Warren, Ph.D.

Project Role: Principal Investigator, VUMC

Research Identifier: eRA Commons - WARRENZE

Nearest person month worked: 0.9

Contribution to Project: Overseeing all intervention-related and administrative aspects of this project including development of intervention program, regulatory requirements (IRB and DSMB) and participation in all cross-site videoconferences, email correspondence and multi-site kick-off meeting.

Name: Lisa Wallace, M.S., CCC-SLP

Project Role: Lead Interventionist

Research Identifier: N/A

Nearest person month worked: 5.0

Contribution to Project: Directing all preparation and development for parent training modules for study participants and developmental effort required for intervention arm of the research protocol with other PIs and co-Investigators. Leading team meetings with entire behavioral staff and participation in all cross-site videoconferences, email correspondence and multi-site kick-off meeting. Directing all aspects of clinical treatment and providing supervision to treatment team.

Name: Amy Weitlauf, Ph.D.

Project Role: Co-Investigator, VUMC

Research Identifier: eRA Commons – AMY.FOLMER

Nearest person month worked: 1.2

Contribution to Project: Assisting the site PI in overseeing the project at the VUMC site, particularly including leading effort to develop assessment procedures, and participate in cross-site videoconferences and email correspondence, and consult on treatment case studies as required.

Name: Amy Swanson, M.A.

Project Role: Study Coordinator, VUMC

Research Identifier: eRA Commons – SWANSOAR

Nearest person month worked: 3.6

Contribution to Project: Forming plan for coordination of all aspects of the study at VUMC including developing recruitment methods, preparing phone scripts and work flow for team members, and assisting PI with identifying lead contacts in local IRB. Coordination of all research visits with families and clinical/research team members, working with diagnostic team throughout recruitment and enrollment procedures, overseeing data management for site.

Name: Will Martin, M.Ed., BCBA

Project Role: Board Certified Behavior Analyst

Research Identifier: N/A

Nearest person month worked: 3.0

Contribution to Project: Planning for parent training modules for study participants and developmental effort required for intervention-related components of the research protocol: coding and fidelity, leading team meetings with RBTs. Supervising RBTs on project, attending meetings with family, clinic director, intervention team, and collection of study data. Assisting Lisa Wallace to direct clinic operations.

Name: Stephanie Kretzer, M.Ed., BCBA  
Project Role: Board Certified Behavior Analyst  
Research Identifier: N/A  
Nearest person month worked: 3.0  
Contribution to Project: Planning for parent training modules for study participants and developmental effort required for intervention-related components of the research protocol: coding and fidelity, leading team meetings with RBTs. Supervising RBTs on project, attending meetings with family, clinic director, intervention team, and collection of study data. Leading TRICARE certification and credentialing requirements for incoming BCBA's and RBTs.

Name: Kate Beuter  
Project Role: Registered Behavioral Technician  
Research Identifier: N/A  
Nearest person month worked: 6.0 (up to 05/29/2020)  
Contribution to Project: Provide one-to-one behavioral intervention to study participants and some intervention-related components of the research protocol: data entry and coding fidelity procedures, attending team meetings with BCBA's and other RBTs.

Name: Jackie Miller  
Project Role: Registered Behavioral Technician  
Research Identifier: N/A  
Nearest person month worked: 6.0 (up to 07/24/2020)  
Contribution to Project: Provide one-to-one behavioral intervention to study participants and some intervention-related components of the research protocol: data entry and coding fidelity procedures, attending team meetings with BCBA's and other RBTs.

Name: Amy Nicholson, MA, LSPE-HSP  
Project Role: Independent Evaluator  
Research Identifier: N/A  
Nearest person month worked: 3.3  
Contribution to Project: Completing all initial training as needed through the study and participation in cross-site evaluator videoconferences and planning meetings, as appropriate for blinded independent evaluators. Providing all diagnostic assessment needs for screened participants.

Name: LaTamara Garrett, M.Ed., BCBA  
Project Role: Board Certified Behavior Analyst  
Research Identifier: N/A  
Nearest person month worked: 0.6  
Contribution to Project: Planning for parent training modules for study participants and developmental effort required for intervention-related components of the research protocol: coding and fidelity, leading team meetings with RBTs. Supervising RBTs on project, attending meetings with family, clinic director, intervention team, and collection of study data.

Name: Marie Martinez, M.S., M.Ed., CCC-SLP, BCBA  
Project Role: Board Certified Behavior Analyst  
Research Identifier: N/A  
Nearest person month worked: 0.2  
Contribution to Project: Planning for parent training modules for study participants and developmental effort required for intervention-related components of the research protocol: coding and fidelity, leading team meetings with RBTs.

Name: Evon Lee, Ph.D.

Project Role: Independent Evaluator

Research Identifier: N/A

Nearest person month worked: 1.8

Contribution to Project: Conducting evaluations of study variables, including cognitive and adaptive functioning and autism symptoms; completing all initial training as needed through the study and participation in cross-site evaluator videoconferences and planning meetings, as appropriate for blinded independent evaluators.

Name: Alacia Stainbrook, Ph.D., BCBA-D

Project Role: TBD

Research Identifier: N/A

Nearest person month worked: 0.2

Contribution to Project: Attending study intervention trainings regarding the MABA intervention arms.

Name: Megan Lanthier

Project Role: Registered Behavioral Technician

Research Identifier: N/A

Nearest person month worked: 6.0 (started 01/13/2020)

Contribution to Project: Provide one-to-one behavioral intervention to study participants and some intervention-related components of the research protocol: data entry and coding fidelity procedures, attending team meetings with BCBA's and other RBTs.

Name: Dzervin Sasic

Project Role: Registered Behavioral Technician

Research Identifier: N/A

Nearest person month worked: 6.0 (started 03/02/2020)

Contribution to Project: Provide one-to-one behavioral intervention to study participants and some intervention-related components of the research protocol: data entry and coding fidelity procedures, attending team meetings with BCBA's and other RBTs.

Name: Tamera Brewer-Edwards

Project Role: Registered Behavioral Technician

Research Identifier: N/A

Nearest person month worked: 6.0 (started 08/24/2020)

Contribution to Project: Provide one-to-one behavioral intervention to study participants and some intervention-related components of the research protocol: data entry and coding fidelity procedures, attending team meetings with BCBA's and other RBTs.

### **University of Rochester Medical Center**

Name: Susan L Hyman, MD

Project Role: Principal Investigator

Research Identifier: ORCID iD 0000-0003-4476-7265

Nearest person month worked: 0.10 cost shared

Contribution to Project: Overall PI of the network; oversees administrative aspects of the project, which includes planning for recruitment, training and conduct of intervention program; assists in meeting regulatory and funding requirements; serves on the cross-site steering committee calls

Name: Suzannah Iadarola, Ph.D.  
Project Role: Investigator  
Research Identifier: ORCID iD 0000-0001-6828-8379  
Nearest person month worked: 0.05  
Contribution to Project: Participates in intervention calls around training, conduct, and supervision; serves on cross-site steering committee calls

Name: Lynne Levato, Ph.D.  
Project Role: Investigator  
Research Identifier: ORCID iD 0000-0002-8005-2892  
Nearest person month worked: 0.05  
Contribution to Project: Participates in assessment calls around training, conduct, and supervision on assessments and independent evaluation; serves on cross-site steering committee calls

Name: Samantha Hochheimer, B.A.  
Project Role: Study Coordinator  
Research Identifier: N/A  
Nearest person month worked: 0.74  
Contribution to Project: Assists in submission and maintenance of IRB; setting up and working with data coordinating and statistics center to maintain database and data quality; planning and training for ensuring compliance with regulations; planning for monitoring site data collection and adherence to regulatory requirements; attends cross-site assessment, intervention, data coordinating, and steering committee calls

Name: Jennifer Dutra, B.A.  
Project Role: Data Manager  
Research Identifier: N/A  
Nearest person month worked: 0.05  
Contribution to Project: Oversee and planning for data quality control; assisting in development of data capture forms; planning to prepare reports for DSMB, funding agency, quarterly reports, etc.; overseeing BLIS integration; discussions with biostatistician for analysis

Name: Hongyue Wang, Ph.D.  
Project Role: Biostatistician  
Research Identifier: N/A  
Nearest person month worked: 0.05  
Contribution to Project: Advises on statistical issues, developing randomization plan, working with data manager for reports, monitor progress of project, and plans to perform statistical analysis

Name: Andrew Watts  
Project Role: Data Team Member  
Research Identifier: N/A  
Nearest person month worked: 0.15  
Contribution to Project: Assists in planning for data quality control, preparing reports, working with biostatistician for analysis, BLIS integration; attends cross-site data coordinating calls

Name: Sarah Farash, Ph.D.  
Project Role: Site Project Manager  
Research Identifier: N/A  
Nearest person month worked: 0.20  
Contribution to Project: Study maintenance and staffing support.

Name: Peter Veazie, Ph.D.  
Project Role: Investigator  
Research Identifier: ORCID iD 0000-0003-4566-7696  
Nearest Person Month Worked: 0.05  
Contribution to Project: Oversee cost analysis measures, ensure that measures are capture cost at study start up, and analyze cost data at study close

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

Nothing to report.

**What other organizations were involved as partners?**

No new partners.

## **8. SPECIAL REPORTING REQUIREMENTS**

**QUAD CHARTS:**

Updated Quad Chart attached.

## **9. APPENDICES:**

None to report.