

AWARD NUMBER: W81XWH-20-1-0171

TITLE: Multicomponent Behavioral Intervention Designed to Increase Functional Independence during Aging in ASD

PRINCIPAL INVESTIGATOR: Nicole L. Matthews, Ph.D.

CONTRACTING ORGANIZATION: Southwest Autism Research & Resource Center (SARRC)  
Phoenix, AZ

REPORT DATE: May 2021

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Development Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE		Form Approved OMB No. 0704-0188
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. <b>PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.</b>		
1. REPORT DATE May 2021	2. REPORT TYPE Annual	3. DATES COVERED 1Apr2020-31Mar2021
4. TITLE AND SUBTITLE  Multicomponent Behavioral Intervention Designed to Increase Functional Independence during Aging in ASD		5a. CONTRACT NUMBER W81XWH-20-1-0171
		5b. GRANT NUMBER AR190103
		5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)  Nicole L. Matthews, Ph.D.; Brittany Blair Braden, Ph.D., Leslie Baxter, Ph.D.  E-Mail: nmatthews@autismcenter.org		5d. PROJECT NUMBER
		5e. TASK NUMBER
		5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Southwest Autism Research and Resource Center (SARRC), 300 N Phoenix, AZ 85006		8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)  U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012		10. SPONSOR/MONITOR'S ACRONYM(S)
		11. SPONSOR/MONITOR'S REPORT NUMBER(S)
12. DISTRIBUTION / AVAILABILITY STATEMENT  Approved for Public Release; Distribution Unlimited		
13. SUPPLEMENTARY NOTES		
14. ABSTRACT Developing and maintaining functional independence in adults with autism spectrum disorders (ASD) across their lifespan is essential to improving quality of life (QoL) and reducing the estimated lifetime costs for these individuals. Our <b>overall objective</b> is to improve independence and QoL in adults with ASD across the lifespan using a single, personalized, multi-faceted, behavioral intervention—Strengthening Skills—that combines the PEERS social skill training program with cognitive compensation training, mindfulness-based emotional regulation, and support group components for those with ASD and their support companions. Our <b>central hypothesis</b> is that independence and QoL can be elevated and Strengthening Skills participants will gain skills in social communication, have improved cognition and enhanced mood. During Year 1, we developed the Strengthening Skills Curriculum combining existing literature with focused interviews with adults with ASD and their support companions. We developed the website that will accompany the instruction, compiled the weekly plan for the Strengthening Skills program, and assembled the program team. With a target start date of August 2021, we are currently recruiting for the first of two cohorts for a pilot prospective, randomized, controlled trial for adults aged 21–70 years diagnosed with ASD who are not intellectually disadvantaged (IQ >70) and their program partner. Two cohorts will be enrolled with a total of 16 ASD–program partner dyads for each of 3 conditions, totaling 48 dyads. To address the need for <b>long-term maintenance of the treatment gains</b> , we are incorporating a website with guided user lessons so that participants are habituated to use the website after training is completed.		

<b>15. SUBJECT TERMS</b>				
Autism Spectrum Disorder; adulthood; aging; behavioral intervention; cognitive compensation; mindfulness; emotional regulation; PEERS social skills intervention; adaptive functioning; quality of life				
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER OF PAGES</b>
<b>a. REPORT</b>	<b>b. ABSTRACT</b>	<b>c. THIS PAGE</b>	Unclassified	11
Unclassified	Unclassified	Unclassified		
			<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRMC	
			<b>19b. TELEPHONE NUMBER</b> <i>(include area code)</i>	

**Standard Form 298 (Rev. 8-98)**  
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction .....	5
2. Keywords .....	5
3. Accomplishments .....	5
4. Impact .....	8
5. Changes/Problems .....	9
6. Products .....	9
7. Participants & Other Collaborating Organizations .....	10

## 1. INTRODUCTION

Developing and maintaining functional independence in adults with autism spectrum disorders (ASD) across their lifespan is essential to improving quality of life (QoL) and reducing the estimated lifetime costs for these individuals. Through our previous DoD funding, we found that middle-age adults with ASD have reduced executive functioning abilities, reduced engagement of functional brain networks during executive function tasks, smaller brain memory structures, and elevated levels of depression and anxiety, compared to neurotypical adults. Also, core ASD symptoms, especially social communication, may worsen with age across the adult lifespan. Thus, the **rationale** for this study is that interventions that improve independence and QoL in adults with ASD across the lifespan will improve the long-term well-being of individuals with ASD and their families, and reduce future costs to society. Our **overall objective** is to improve independence and QoL in adults with ASD across the lifespan using a single, personalized, multi-faceted, behavioral intervention—Strengthening Skills—that combines the PEERS social skill training program with cognitive compensation training, mindfulness-based emotional regulation, and support group components for those with ASD and their support companions. Our **central hypothesis** is that independence and QoL can be elevated in this population and Strengthening Skills participants will gain skills in social communication and have improved cognition and enhanced mood. We first developed the Strengthening Skills Curriculum through a review of existing literature and focused interviews with 5 adults with ASD and 4 of their support companions. During Year 1, we developed the Strengthening Skills Curriculum combining existing literature with focused interviews with adults with ASD and their support companions. We developed the website that will accompany the instruction, compiled the weekly plan for the Strengthening Skills program, and assembled the program team. With a target start date of August 2021, we are currently recruiting for the first of two cohorts for a pilot prospective, randomized, controlled trial for adults aged 21–70 years diagnosed with ASD who are not intellectually disadvantaged (IQ >70) and their program partner. Two cohorts will be recruited with a total of 16 ASD–program partner dyads for each of 3 conditions, totaling 48 dyads. To address the need for **long-term maintenance of the treatment gains**, we are incorporating a website with guided user lessons so that participants are habituated to use the website after training is completed.

## 2. KEYWORDS

Autism Spectrum Disorder; adulthood; aging; behavioral intervention; cognitive compensation; mindfulness; emotional regulation; PEERS social skills intervention; adaptive functioning; quality of life

## 3. ACCOMPLISHMENTS

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

- **Specific Aim 1:** Evaluate the effectiveness of a multi-faceted, ASD–support companion dyad intervention including social communication, cognitive compensation, and emotional regulation training (Strengthening Skills; previously PEERS-plus), for improving functional independence as measured by the Adaptive Behavior Assessment System-Third Edition (ABAS-3).
- **Specific Aim 2:** Evaluate the effectiveness of the Strengthening Skills intervention for improving QoL in adults with ASD and their support companion.
- **Specific Aim 3:** Evaluate skill gains using measures that reflect specific components of the PEERS-plus intervention.

## **Proposed phases, milestones, and target dates:**

*Phase 1 (Year 1): Program Development.* Aims: 1) Program development for behavioral intervention (Strengthening Skills, previously PEERS-plus) and revise based on focused interviews. 2) Prepare Strengthening Skills website. 3) Assemble and train the treatment team.

- **Milestones**

- *Local IRB approval for focus interview protocol – Target date: 6/30/2020; Percentage of completion: 100%; Completion Date: 3/15/2020*
- *HRPO approval for focus interview protocol – Target date: 9/30/2020; Percentage of completion: 100%; Completion Date: 7/31/2020*
- *Students trained on Strengthening Skills and PEERS protocols – Target date: 4/30/2021; Percentage of completion: 20%*

*Phase 2: Implementation of Strengthening Skills, PEERS, and delayed-treatment interventions:* Aim: 1) Execute the protocol comparing Strengthening Skills, PEERS, and a waiting list control two times.

- **Milestones**

- *Complete two interventions – Target date: 11/30/2022; Percentage of completion: 0%*
- *Report results from data analyses; design larger trial based on findings: Target date – 3/30/2023; Percentage of completion: 0%*

## **What was accomplished under these goals?**

### **Major Activities**

#### **A) IRB, HRPO approval and oversight**

The IRB protocol and associated documents were developed and submitted by the Principal Investigators to ASU's IRB. After IRB approval for the focused interviews and the intervention study was obtained, the HRPO protocol submission form and supporting documents were submitted to and approved by the HRPO. A modification to the study protocol to allow for administration of focused interviews through teleconferencing was approved by Arizona State University IRB and the HRPO on 8/31/2020.

#### **B) Development of the Strengthening Skills Curriculum**

We proposed to develop a multi-component intervention adapted from the Mayo-based HABIT curriculum for older adults (i.e., cognitive compensation strategies for individuals with Mild Cognitive Impairment), the PEERS for Young Adults Curriculum (i.e., social skills), and Mindfulness Based Stress Reduction. The first year of the award was dedicated to developing and refining the proposed intervention based on published literature, focused interviews with autistic adults and their support companions, and consultation with experts in various relevant fields. Dr. Matthews, Dr. Braden, and Dr. Baxter met regularly and as a team and met with both consultants on the project (Dr. Dona Locke and Dr. David Coon). We designed a template of the intervention and refined the intervention protocol based on information obtained through comprehensive focused interviews. Dr. Matthews completed individual 90-minute focused interviews with five adults with autism and four support companions. Drs. Braden and Baxter reviewed the focused interviews and the team met to discuss details to be incorporated from the interviews, and adapted the Strengthening Skills modules accordingly. The study team also consulted with Dr. Chad Stetcher, a behavioral health economist at Arizona State University, to discuss evidence-based strategies for forming health-promoting habits and how these

strategies could be integrated into the Strengthening Skills modules. As a result of our focused interviews and consultation with others, we changed the name of our personalized intervention from “PEERS Plus” to “Strengthening Skills”, which provides a more specific and positive label for the training. Dr. Matthews completed PEERS for Young Adults certified provider training through the UCLA PEERS clinic and revised PEERS materials to reflect the adaptations developed based on the focused interviews. Dr. Braden developed the Mindfulness Based Stress Reduction program integration and coordinated with instructors and Speech Language Pathology students who will participate in this aspect of the training program. Thus, our first stated goal of finalizing the Strengthening Skills protocol, design and materials and preparing PEERS materials and assessments was met.

### **C) Website development**

An employment contract was established with a web developer for the companion website for the intervention. Dr. Braden and the website developer coordinated with ASU’s information technology office to determine logistics for maintenance of the website. The website developer created a template of the website that is currently being updated with final content for the program. Additionally, the study team met with the website developer and the biostatistician (Dr. O’Rourke) to identify the method by which backend website data will be collected and analyzed. For the stated goal: Prepare website with PEERS-plus modules (Basic website design and insertion of modules when completed; Target date: 3/31/21; Percentage of completion: 75%), we experienced a slight delay in completion due to some early obstacles faced when communicating with ASU’s information technology office. However, we will have the website completed and functional by July of 2021 (one month prior to the start of the interventions).

### **D) Preparation for clinical trial**

In addition to developing the Strengthening Skills program, we completed multiple activities to prepare for the clinical trial that will begin in year 2 (August 2021). The study team met with the biostatistician, Dr. O’Rourke, to finalize the recruitment strategy and plans for stratifying participants by age, gender, and adaptive functioning scores prior to randomization. Additionally, a timeline for baseline and post-intervention data collection was developed. Dr. Matthews submitted the study to [clinicaltrials.gov](http://clinicaltrials.gov) and trained Ms. Shanna Delaney, the study coordinator, on the phone screening script and informed consent process. Dr. Braden met with internship coordinators for ASU’s Speech and Language Pathology program to identify students to assist with the delivery of the interventions. The study team created a training schedule for student interns and Dr. Matthews developed a collection of recordings of PEERS sessions for training purposes.

### **E) Other Related Accomplishments**

Our focus on adaptive functioning in adults has expanded in the last year. Drs. Matthews and Smith completed data analysis from a mixed-methods study examining adaptive functioning in autistic young adults. The study, which involved qualitative analysis of semi-structured interviews with young adults and their parents, was recently **accepted for publication in *Autism: International Journal of Research and Practice***. This study identified specific needs and considerations for working with autistic adults, which informed the development of the Strengthening Skills protocol. Specifically, themes identified suggest that interventions focus on helping adults achieve interdependence in their communities rather than complete independence, that adults may face multiple interruptions to independence, which could require support from family and public services, and that many adults know how to complete most self-care and domestic tasks but have difficulty with initiating and managing them. Findings also identified the importance of balancing helpful and harmful parent involvement and the need for autistic adults to focus on safety online and in the community. We used these findings as starting points to determine the similarities and differences of the needs of adults with ASD of different ages when designing the focused interviews with older autistic adults and their support companions as a part of the current project.

During the last year, **Dr. Braden published two papers that influenced the development of the present study**. First, we found that mindfulness-based stress reduction improved depressive symptomatology in adults

with ASD and identified related-brain changes (Pagni et al., 2020, Journal of Neuroscience Research). This work helped us identify the most salient aspects of the mindfulness program to emphasize in Strengthening Skills for adults with ASD, and highlighted the need to include depression as a secondary study endpoint. Second, in a cross-sectional study we found that women with ASD may improve in social cognition as they age whereas men may decline (Pagni et al., 2020, Frontiers in Integrative Neuroscience). This helped inform our study design to balance sex across groups for Strengthening Skills and the need to explore secondary analyses on effects of sex.

Dr. Matthews has strengthened her experience of PEERS training in adults during the pandemic when she **transitioned SARRC's PEERS program for teens to virtual delivery**. Dr. Matthews utilized resources provided by the UCLA PEERS clinic, and also information she learned at the UCLA PEERS for Young Adults training, to successfully deliver PEERS through Zoom to two cohorts of families ( $n = 14$ ). The knowledge and skills gained from this experience will be particularly useful as we deliver the Strengthening Skills and PEERS programs virtually to the first cohort in the current study.

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

Training and professional development was not a major goal of this project; however, Dr. Smith is a formal mentor for Dr. Braden through an NIH K01 Career Development Award. Further, both Drs. Matthews and Braden are attending a training on the Adaptive Behavior Assessment System™, Third Edition, which is a primary endpoint in the current study and a part of Dr. Braden's K01 training plan. Lastly, Dr. Braden mentors two PhD, two Master's, and six undergraduate students that have all gained foundational knowledge in intervention development through lab meetings over the course of this project.

### **How were results disseminated to communities of interest**

- **Nothing to Report**

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

- We will finalize the Strengthening Skills the website within the first four months of the next reporting period (by July 2021).
- We will train the students assisting with the intervention on the Strengthening Skills and PEERS protocols in July/August of 2021.
- We will recruit participants for the first cohort from April to July of 2021. We will conduct baseline data collection visits in July of 2021 prior to randomizing participants in August of 2021. We will continue to recruit participants for the second cohort from August to December of 2021 and will conduct baseline data collection visits for this cohort in January of 2022.
- We will deliver the intervention to the first cohort of participants from August – December of 2021 and the second cohort of participants from February to May of 2022.
- We will collect post-treatment data from all participants and ensure data is entered efficiently and accurately.
- We will prepare to deliver the intervention to delayed treatment control group participants in Year 3 of the award.

## **4. IMPACT**

### **Principal Disciplines**

- **Nothing to Report**



## **Other Disciplines**

- **Nothing to Report**

## **Technology Transfer**

- **Nothing to Report**

## **Society Beyond Science and Technology**

- **Nothing to Report**

## **5. CHANGES/PROBLEMS**

### **Changes in approach and reasons for change**

Due to the COVID-19 pandemic, focused interviews were conducted through videoconferencing rather than in-person. Additionally, because it remains uncertain whether it will be accepted by the cohort to conduct a group intervention in-person in August of 2021, we decided to deliver the intervention to the first cohort of participants through Zoom meetings rather than in-person. Virtual delivery of group interventions for teens and adults with ASD has become commonplace since the onset of the pandemic and Dr. Matthews has experience delivering the PEERS program to two cohorts of teens and their parents using this modality.

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

Due to ASU student assistant schedules, we had to delay the start of the first cohort from June to August of 2021. Fortunately, the original project timeline included a buffer which will allow for this delay without disrupting the completion of the project goals. As discussed in the change of approach section above, the COVID-19 pandemic prevented in-person data collection during the first year and will prevent in-person delivery of the intervention for at least the first cohort of participants. To resolve this problem, we have used and plan to continue using videoconferencing technology. We also experienced some initial difficulties coordinating website server details with the ASU Information Technology department, but with resolution of this, we are on track to complete the website by the start of July and well ahead of the start of the first intervention trial.

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

Nothing to Report.

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

Due to the pandemic, we incorporated the use of videoconferencing to the approved protocol, which was approved by both ASU's IRB and HRPO. An initial modification for the focused interviews was approved by ASU's IRB on 8/4/2020 and a second modification for the intervention was recently approved by ASU's IRB on 4/20/2021.

## **6. PRODUCTS**

### **Publications, conference papers, and presentations**

- **Nothing to Report**

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

- **Nothing to Report**

### **Technologies or techniques**

- **Nothing to Report**

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

- **Nothing to Report**

## Other products

- Nothing to Report

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals worked on the project?

*Name:* Nicole Matthews

*Project Role:* Principal Investigator

*Researcher Identifier (e.g. ORCID ID):* 0000-0001-7433-1142

*Nearest person month worked:* 4

*Contribution to Project:* Dr. Matthews worked on obtaining IRB and HRPO approval, submitting IRB and HRPO amendments, developing materials for the Strengthening Skills intervention, conducting and reviewing the focused interviews, attending the PEERS for Young Adults Certified Provider Training, training the study coordinator, and developing a training plan for Strengthening Skills and PEERS clinicians.

*Name:* Blair Braden

*Project Role:* Co-Principal Investigator

*Researcher Identifier (e.g. ORCID ID):* [0000-0001-6842-9784](#)

*Nearest person month worked:* 4

*Contribution to Project:* Dr. Braden worked on obtaining IRB and HRPO approval, submitting IRB and HRPO amendments, developing materials for the Strengthening Skills intervention, reviewing the focused interviews, identifying student interns to support delivery of the programs, developing a training plan for Strengthening Skills and PEERS clinicians, and supported the web designer in the development of the website.

*Name:* Leslie Baxter

*Project Role:* Co-Investigator

*Researcher Identifier (e.g. ORCID ID):* 0000-0002-3971-863X

*Nearest person month worked:* 4

*Contribution to Project:* Dr. Baxter worked on developing materials for the Strengthening Skills intervention, reviewing the focused interviews, and developing a training plan for Strengthening Skills and PEERS clinicians.

*Name:* Shanna Delaney

*Project Role:* Lab Coordinator

*Researcher Identifier (e.g. ORCID ID):* 0000-0002-7338-6579

*Nearest person month worked:* 6

*Contribution to Project:* Ms. Delaney assisted the principal investigators with the communication with ASU's IRB as the study team responded to HRPO inquiries and submitted the study amendment. She also recruited, screened, scheduled, and consented focused interview participants and received training in recruitment and consenting participants for the clinical trial.

*Name:* Holly O'Rourke

*Project Role:* Co-Investigator

*Researcher Identifier (e.g. ORCID ID):* 0000-0002-2927-0333

*Nearest person month worked:* 2

*Contribution to Project:* Dr. O'Rourke met with the web designer PIs and Co-Is to identify the method by which backend website data will be collected and analyzed. She also met with the PIs and Co-Is to identify a plan for baseline and post-treatment data collection and stratification of participants by age, gender, and adaptive functioning scores prior to randomization.

**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. Matthews' active support changed in that she receives 1.2 person months of support from the Flinn Foundation for a study examining the impact of COVID-19 public health measures on the experiences of individuals with ASD and their family members. The award period for this grant is 7/1/2020 – 6/30/2021.

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

**Organization Name:** Arizona State University

**Location of Organization:** 975 S. Myrtle Ave., Tempe, AZ 85281

**Partner's contribution to the project:** Co-PI subaward; Biostatistician

**Collaboration:** Recruitment of participants; collaboration with development of the Strengthening Skills Protocol and website; data interpretation and manuscript preparation

**Organization Name:** Mayo Clinic Arizona

**Location of Organization:** 5777 East Mayo Blvd, Phoenix, AZ 85054

**Partner's contribution to the project:** Co-I subaward

**Collaboration:** Collaboration with development of the Strengthening Skills Protocol and website; data interpretation and manuscript preparation