

AWARD NUMBER: W81XWH-20-1-0171

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

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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 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 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 a website that accompanied the instruction, compiled the weekly plan for the Strengthening Skills program, and assembled the program team. During years 1 and 2, we successfully recruited two cohorts for a pilot prospective, randomized, controlled trial for 42 autistic adults aged 21–70 years who are not intellectually disadvantaged (IQ >70) and their program partners. We completed treatment delivery to treatment groups for cohort 1 in year 2 and completed treatment delivery to treatment groups for cohort 2 in year 3. Treatment delivery to the delayed treatment control group began in year 3 and was completed in March of 2023 (Year 4; No Cost Extension).		

15. SUBJECT TERMS					
Autism Spectrum Disorder; adulthood; aging; behavioral intervention; cognitive compensation; mindfulness; emotional regulation; PEERS social skills intervention; adaptive functioning; quality of life					
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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 support costs. 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. During year 1, 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. We developed the website that accompanies instruction, compiled the weekly plan for the Strengthening Skills program, and assembled the program team. In years 1 and 2, we recruited participants for two cohorts for a pilot prospective, randomized, controlled trial for autistic adults aged 21 and older who are not intellectually disadvantaged ($IQ > 70$) and their program partner (if available). A total of 42 adults with ASD were recruited and randomly assigned into one of three conditions: Strengthening Skills ($n = 14$), PEERS for Adults ($n = 14$), or delayed treatment control (DTC; $n = 14$). To address the need for **long-term maintenance of the treatment gains**, we incorporated a website with guided user lessons so that participants are habituated to using supports after training is completed. This intervention is part of our larger work in understanding autistic needs across the adult lifespan and developing effective interventions.

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: 100%; Completion Date: 8/1/2021*

Phase 2 (Years 2-3): 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: 100%*
- *Report results from data analyses; design larger trial based on findings: Target date – 3/30/2023; Percentage of completion: 50%*

What was accomplished under these goals?

Major Activities

A) IRB, HRPO approval and oversight

- The following amendments to the study protocol were approved by Arizona State University IRB on 9/14/2022 and submitted to HRPO on 9/15/2022.
 1. The protocol was updated to reflect that all participants will complete the interventions virtually (i.e., through Zoom).
 2. Because the intervention protocol has been modified significantly based on feedback from participants in previous cohorts, we would like to collect pilot effectiveness data from participants in the DTC group who go through the most recent iteration of the program.
The protocol was edited to include two additional time points for participants in the delayed treatment control group who enroll in the intervention after their wait period. We will collect data from participants at intervention midpoint and exit. Participants who complete these time points will receive an additional \$50 compensation.
 3. We have edited the consent form to include these additional time points and payment. Delayed treatment control group participants who enroll in the intervention will be reconsented before starting the intervention.
- ASU IRB approved continuation of the study protocol on 3/08/2023 and HRPO on 3/21/2023.

- The following amendments were approved by ASU’s IRB on 3/17/2023. Amendments were not substantive, so they were not submitted to HRPO for review.

1) Study team member update.

B) Development and Delivery of the Strengthening Skills Curriculum

We proposed to develop a multi-component intervention adapted from the Mayo-based HABILIT 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. Our first stated goal of finalizing the Strengthening Skills protocol, design and materials and preparing PEERS materials and assessments was met during Year 1.

During the second year of the award, we delivered the Strengthening Skills program or the PEERS program to the first cohort of treatment group participants. This included weekly 3-hour or 1.5-hour group meetings, respectively, for 16 weeks (PEERS group: 24 hours of intervention; Strengthening Skills group: 48 hours of intervention). The treatment team, including Dr. Matthews (PEERS content), Dr. Baxter (executive skills module), Ms. Lisa Ballard (mindfulness training), Ms. Maria Dixon (Speech and Language Pathology students’ supervisor), Ms. Melissa Mitchell (PEERS instructor), Speech and Language graduate students, and undergraduate students (fidelity checkers), participated in weekly 2-hour preparation meetings, during which the team reviewed cases and prepared for the upcoming week. We collected feasibility and acceptability data, including participant acceptability surveys at intervention midpoint and exit. These data were used to revise the programs for the second cohort.

During the second and third year of the award, we delivered the Strengthening Skills program or the PEERS program to treatment group participants in Cohort 2 (PEERS group: 24 hours of intervention; Strengthening Skills group: 48 hours of intervention). The treatment team continued weekly 2-hour meetings to review cases and prepare for the upcoming week. Again, we collected feasibility and acceptability data, including participant acceptability surveys at intervention midpoint and exit. These data were used to further revise the program for delayed treatment control group participants.

We used the third award year to implement a modified treatment based on feedback from the acceptability data obtained by Cohorts 1 & 2 to the delayed treatment group. Since we were no longer comparing our intervention with the PEERS program, we were able to have shortened classes of 2 hours, with equal distribution of executive functioning/compensation, mindfulness and social skills training. During the third year of the award (and first month of the fourth year), delayed treatment control group participants completed the revised Strengthening Skills program (32 hours of intervention).

C) Website development

In year 1, 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. We experienced a slight delay in completion due to some early obstacles faced when communicating with ASU’s information technology office. However, the website was completed and functional by July of 2021. 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: 100%), The website was revised after the first and second cohort completed the program to reflect revisions to the program.

D) Implementation of clinical trial

In year 1, 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 and trained Ms. Shanna Delaney, the study coordinator, on the phone screening script and informed consent process.

In year 2, Ms. Shanna Delaney recruited and phone screened 88 potential participants for eligibility. Dr. Matthews and SARRC staff conducted intake study visits with 46 participants; 42 autistic adults completed baseline study visits with SARRC staff and were randomized to a study condition. SARRC staff conducted follow up study visits with 20 of 21 participants in cohort 1 (1 participant was lost to attrition). When autistic adults were able to identify a study partner, study partners completed questionnaires remotely at baseline and follow-up study visits.

In year 3, SARRC staff conducted follow up visits with 13 of 21 participants in cohort 2 (8 participants were lost to attrition). Additionally, with supervision from Drs. Braden and Matthews, Ms. Delaney contacted participants from Cohorts 1 and 2 for their 3- and 6-month data collection, which was conducted remotely.

E) Other Related Accomplishments

During year 1, Drs. Matthews and Smith published 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 **published 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. Additionally, Dr. Matthews presented findings from this study at the annual conference of the Autism Society of Greater Phoenix (virtual event) and through a webinar hosted by one of SARRC's community partners.

During year 1, **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. In year 2, **we have continued to published on sex differences in mental and physical health-related quality of life and responses to mindfulness-based stress reduction intervention (Braden et al., 2021), social communication challenges (Walsh et al., 2021), and social compensatory behavior (i.e. "camouflaging"; Walsh et al., 2022) in autistic adults across the lifespan.** These findings further emphasize the importance of considering sex differences in intervention response for autistic adults as well as guide appropriate outcome

measures for our exploratory analyses. Finally, we have published preliminary findings on the effects of **mindfulness-based stress reduction on emotion regulation in autistic adults (Pagni et al., 2021)**, which further emphasizes the utility of this program for this population. In year 3, we were **the first to publish longitudinal cognitive and brain aging findings in middle-age and older autistic adults** compared to matched controls. In a series of two papers we identified vulnerabilities for **accelerated decline in short- and long-term memory as well as memory brain structures (Pagni et al., 2022; Walsh et al., 2022)**. These findings have guided an increased focus on memory compensation strategies for midlife and older autistic adult participants of the Strengthening Skills Program. Lastly, we published new findings **that mindfulness-based stress reduction is associated with executive function improvements** in autistic adults, compared to an active control intervention (Pagni et al., 2023).

During year 3, Drs. Matthews and Braden received funding from the Blue Cross Blue Shield of Arizona Foundation for Community and Health Advancement to develop and test a mindfulness-based telehealth intervention for adolescents with autism and their caregivers. The intervention, named MINDful TIME, **combines aspects of the Strengthening Skills Program (habit formation; mindfulness strategies) with use of a commercially available mindfulness mobile app that Dr. Braden's lab has used in multiple studies with autistic adults**. We began recruiting and enrolling participants for this study in January of 2023 and the pilot study is estimated to be completed by January of 2024. To better understand the biological aspects of aging risks in autistic adults, **Dr. Braden was awarded a two-year pilot grant through the NIH-funded Arizona Alzheimer's Disease Research Center (P30 AG072980) to elucidate the influence of Alzheimer's disease risk genes on aging outcomes in autistic adults**.

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. Over the course of this award, Dr. Braden mentored five PhD, five Master's, and 20 undergraduate students that have all gained foundational knowledge in intervention development and delivery through lab meetings and/or collecting intervention fidelity data during the course of this project. Five additional graduate students in Speech and Hearing Sciences at ASU gained training in the delivery of PEERS and/or Strengthening Skills through an internship placement with our treatment team.

How were results disseminated to communities of interest

- Drs. Matthews, Braden, and Baxter submitted an abstract describing the development of the Strengthening Skills Program and feasibility and acceptability data to the annual meeting of the International Society of Autism Research (INSAR). The abstract was accepted and will be presented at the conference in May of 2023.
- Dr. Matthews presented preliminary findings regarding the adaptation of PEERS for adults of all ages at the annual conference of the Phoenix Chapter of the Arizona Autism Society.
- Dr. Braden delivered an invited talk at the Arizona Bioethics Network Annual Conference where she described the development of the Strengthening Skills Program and feasibility and acceptability findings in April 2023.

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

- We will present effectiveness data at a minimum of one local and one national/international conference.
- We will submit a minimum of two manuscripts to peer-reviewed journals.
- We will begin writing grant applications to fund a larger, randomized controlled trial of the Strengthening Skills program. We are currently preparing a letter of intent for FY2023 CDMRP Autism Research Program Clinical Trial 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, we delivered the intervention 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 four cohorts of teens and their parents using this modality. Open-ended responses from acceptability surveys suggest that some participants would prefer to participate in the program in-person, but generally understand that virtual delivery is necessary due to current circumstances. Other participants indicated that they appreciated virtual delivery because it allowed them to participate in the comfort of their own home.

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

As discussed in the change of approach section above, the COVID-19 pandemic prevented in-person delivery of the intervention. To resolve this problem, we have used and plan to continue using videoconferencing technology. We had some COVID-19-related attrition in our cohorts but we over-recruited in anticipation of some attrition; therefore, our actual sample size of participants that completed data collection at time points 1 and 2 ($n = 33$ autistic adults) was close to our target sample size ($n = 36$).

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 approved by ASU's IRB on 4/20/2021.

6. PRODUCTS

Publications, conference papers, and presentations

Matthews, N. L., Gallegos, S., Hill, E., Pagni, B., Delaney, S., Mitchell, M., Zerga, L., Cortes Coria, S., Ogbeama, D., O'Rourke, H., Baxter, L., & Braden, B. B. (2023, May). *Supporting Quality of Life in Autistic Adults of All Ages: Development of the Strengthening Skills Program*. To be presented at the 2023 Annual Meeting of the International Society for Autism Research.

Hill, E., Gallegos, S. Ogbeama, D. Cortes Coria, S., Delaney, S., Pagni, B., O'Rourke, H., Dixon, M.V., Baxter, L.C., Matthews, N., Braden, B.B. The Development of the Strengthening Skills Program for Autistic Adults: Feasibility & Acceptability. ASU College of Health Solutions Student Research Symposium, April 28, Phoenix, AZ

Braden, B. B. (2023, April). *Understanding Aging in Autistic Adults and Developing Meaningful Supports*. Arizona Bioethics Network Annual Conference. April 14, 2023

Matthews, N. L., Baxter, L. C., & Braden, B. B. (2022, September). *PEERS Social Skills Program for Adults of All Ages*. Global Autism Conference of the Autism Society of Greater Phoenix, Virtual.

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 submitting IRB and HRPO amendments and renewals, analyzing feasibility and acceptability data, revising materials for the Strengthening Skills intervention based on acceptability data, training Strengthening Skills and PEERS assistants, and supervising SARRC staff who administered time 2 follow-up visits. Dr. Matthews coordinated with ASU staff as they completed time 3 and time 4 data collection. She supervised delivery of the PEERS and Strengthening Skills weekly meetings and served as the PEERS group or program partner group leader for both programs. She is also contributing to the development of future grant applications.

Name: Blair Braden
Project Role: Co-Principal Investigator
Researcher Identifier (e.g. ORCID ID): [0000-0001-6842-9784](https://orcid.org/0000-0001-6842-9784)
Nearest person month worked: 2

Contribution to Project: Dr. Braden worked on submitting IRB and HRPO amendments and renewals and revising materials for the Strengthening Skills intervention. Dr. Braden supervised Ms. Delaney and research assistants as they conducted Time 3 and 4 data collection with participants and their program partners. She also supervised Ms. Delaney and ASU research assistants as they cleaned data and supervised ASU graduate student research assistants as they worked with Dr. O'Rourke to analyze pilot effectiveness data. Dr. Braden developed a protocol for a Community Advisory Board of autistic adults who will provide feedback to our study team as we disseminate findings, finalize the intervention manual, and apply for additional grant funding. She is also contributing to manuscript preparation and the development of future grant applications.

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 contributed to revising materials for the intervention and contributed to development of the companion website. Dr. Baxter led the cognitive compensation component of the Strengthening Skills program and provided supervision for staff and students implementing the PEERS and Strengthening Skills programs. She is also contributing to the development of future grant applications.

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 assisted with coordination of follow-up data collection and data cleaning.

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 analyzed pilot effectiveness data and mentored graduate research assistants in Dr. Braden's lab as they assisted with data analysis.

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

Blue Cross Blue Shield of Arizona (BCBSAZ) Foundation for Community and Health Advancement
Matthews (PI), Braden (Co-PI)
1/2023-12/2023

Investigating a Mindfulness Intervention to Reduce Anxiety and Depression in Teens with ASD and Caregivers

P30 AG072980, National Institute on Aging Developmental Project grant (Total Costs: \$120,000)
Braden (PI)

7/1/2022 – 6/30/2024

The Influence of Alzheimer's Disease-Associated Genetics on Aging with Autism Spectrum Disorder

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