

**AWARD NUMBER:** W81XWH-18-1-0284

**TITLE:** A Randomized Controlled Trial of the Emotion Awareness and Skills Enhancement (EASE) Program for ASD

**PRINCIPAL INVESTIGATOR:** Carla A. Mazefsky, Ph.D.

**CONTRACTING ORGANIZATION:** University of Pittsburgh

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

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<b>6. AUTHOR(S)</b> Carla A. Mazefsky, Ph.D.  E-Mail: <a href="mailto:mazefskyca@upmc.edu">mazefskyca@upmc.edu</a>		<b>5d. PROJECT NUMBER</b>
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		<b>5f. WORK UNIT NUMBER</b>
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  University of Pittsburgh (Pitt) 3811 O'Hara St. Webster Hall, Suite 300 Pittsburgh, PA 15213		<b>8. PERFORMING ORGANIZATION REPORT</b>
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**14. ABSTRACT**

The **primary objective** of this study is to formally evaluate efficacy of the Emotion Awareness and Skills Enhancement (EASE) program via a sufficiently powered, two-site randomized-controlled trial (RCT). This is consistent with several FY17 ARP areas of interest, namely: (1) EASE is a behavioral, non-pharmacological therapy that (2) alleviates co-occurring conditions (EASE aims to decrease, depression, anxiety, and aggression by improving ER), and (3) promotes success during the transition to adulthood. **The Specific Aims** include: Aim 1 (Primary Outcome): Show that EASE improves ER; Aim 2 (Secondary Outcomes): Demonstrate that EASE results in decreased functional impairment and reduced psychiatric symptoms and problem behaviors; Aim 3 (Durability): Examine the trajectory of change including the degree to which effects are sustained after treatment completion; Aim 4 (Exploratory - Mediators): Evaluate whether changes in ER and mindfulness mediate improvements. Hypotheses: We hypothesized that EASE will improve ER, decrease psychiatric symptoms and problem behaviors, and reduce functional impairment, and that the effects will be sustained. Currently, we have completed Year 4 of this four-year project near our projected recruitment targets, with 195 of 200 participants recruited, 128 participants screened, 113 enrolled, and 76 who have already completed the study.

**15. SUBJECT TERMS**

Autism Spectrum Disorder; emotion regulation; mindfulness; awareness; emotion management

<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER OF PAGES</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRDC
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**1. INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

There are very limited treatment options for adolescents and adults with ASD, and no psychosocial interventions to support healthy emotional functioning and reduce problem behaviors that span the transition from adolescence to adulthood. To address this significant treatment need, we developed the Emotion Awareness and Skills Enhancement (EASE) Program. EASE is a 16-week individual therapy program for verbal adolescents and young adults with ASD, designed to improve emotion regulation (ER) capacity. EASE emphasizes awareness of one’s own emotional responses as a foundational skill that promotes the ability to manage intense negative emotions, which is taught through mindful awareness. Once increased emotional self-awareness is improved, the therapist works with the client to build his/her tolerance for distress through different strategies for emotion management. Targeting impaired ER during adolescence and young adulthood in ASD should improve psychiatric concerns, problem behaviors, and functional outcomes. This developmental period (ages 12-21) represents a heightened time of risk for emergence of co-occurring mental health problems, and is thus a critical time to intervene. Based on data from a pilot study of EASE, we have evidence that it is both feasible to implement and acceptable to participants; moreover, we have observed improvements in emotional functioning and problem behaviors, and decreased functional impairment. Given these promising preliminary data, the next step is to evaluate EASE’s efficacy through a randomized controlled trial. The primary objective of this study is to formally evaluate efficacy of EASE via a sufficiently powered, two-site randomized-controlled trial (RCT). EASE’s mechanism-focused emphasis on ER should promote dissemination and adoption of evidence-based approaches in practice (e.g., a single intervention for a variety of concerns). Finally, because ER plays a critical role in functioning across all domains of life, we expect EASE to result in improvements in adaptive functioning at work/school and in the family, and to improve readiness for transition into adulthood.

**2. KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Autism Spectrum Disorder; emotion regulation; mindfulness; awareness; emotion management

**3. ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

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

*List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.*

**What was accomplished under these goals?**

*For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project*

*progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.*

Our established goals for the fourth year of the project continued to be disrupted somewhat by the COVID-19 pandemic; however, we have continued to adapt our procedures as needed so that we can continue our project. We requested, and hope to receive, a no-cost extension for the project. We have stopped new enrollment but have participants still in treatment. We anticipate all participants being done with the post-treatment assessments by the end of 2022, allowing us to finish collection of follow-up assessments and complete analysis and submission of our final manuscript in the first half of 2023.

The SOW listed the following goals for the fourth year of the project, and progress that has been made is listed below:

**Task 1: Trial Infrastructure**

- IRB renewed in November 2021
  - IRB amendments were approved in spring 2020 to conduct therapy and assessment via telehealth and to adapt in-person participant visits for adherence to institutional standards for COVID-19 safety. While we have returned to in-person therapy visits for most of our participants, we continue to offer the telehealth option for participants and their families.
- HRPO approval obtained in October 2018
  - HRPO was alerted when we paused participant visits due to COVID-19 and was kept up to date when modifications were made to adapt to the pandemic.

**Task 2: Coordinate and Train Study Staff for Clinical Trials\***

- Clinician training: Weekly site-specific and cross-site clinical supervision of both treatments were established by month 6 and are ongoing. Note: we paused both weekly cross-site supervision and site-independent weekly supervision from March 16- April 24, 2020, while sessions were paused. Supervision has since resumed and continues remotely.
- Assessor and treatment-naïve rater training and on-going reliability procedures were established by month 6 and are ongoing remotely.
- Student RAs were trained by month 6 to monitor fidelity to treatment delivery; rating of 20% of treatment videos is up to date and ongoing.

**Task 3: Participant Recruitment\***

- Recruitment began at the start of study and completed in June 2022 (we extended recruitment past Year 3 in order to meet original recruitment goals).
- We have completed enrolling participants as of June 2022: Year 1-4 Number Recruited= 195; Number Screened= 128; Number Enrolled= 113; Number Completed= 76

**Task 4: Therapy and Participant Evaluation\***

- All participants' eligibility and pre-treatment assessments are complete as of July 2022; midpoints, post-treatments, and 3-month follow-ups are ongoing. From March 16, 2020 until August 3, 2020, we obtained all pre-treatment, midpoint, post-treatment, and 3-month follow-ups online. Beginning August 3, 2020, we offered the option of administering assessment appointments in-person or online based on participant choice.

- Treatment sessions have been conducted at both sites and the provision of study treatments is ongoing. Sessions were paused from March 16- April 24, 2020. We sought and obtained IRB approval to continue with treatment sessions via telehealth. We offered participants the choice of online or in-person sessions beginning on August 3, 2020.
- Participant progress has been reviewed at weekly on-site local supervision and weekly cross-site supervision and is ongoing; Participant status has been monitored at weekly site meetings and is ongoing.
- Data entry has been entered into database and is ongoing. During the pause in data collection in 2020, staff audited the databases to ensure that timepoints are accurate and that scores are correctly calculated. Corrections were made as needed.
- Direct assessment data has been cleaned following double entry (not needed for direct entered questionnaire data into WDX).

#### **Task 5: Data analysis**

- We have focused on cleaning all data and creating final databases for all eligibility and baseline data, since those timepoints are completed.
- Our statistician has initiated the following:
  - Analysis of baseline scores to confirm that randomization procedures are working as intended, which they are
  - Data cleaning and determination of who meets per protocol criteria
  - Preliminary analysis of outcomes
    - As of May 2022, both groups demonstrate improvements, with large effect sizes in the EASE group
    - Preliminary analyses confirm significant beneficial effects of EASE, such as stronger reductions in dysphoria (between condition Cohen's  $d = 0.56$ ,  $p = .04$ ), improved mindfulness ( $d = .62$ ,  $p = .02$ ), and improved functional outcomes ( $d = .76$ ,  $p = .02$ ) compared to the supportive therapy condition.

#### **Task 6: Dissemination and Transition**

- We submitted a letter of intent for a PCORI PFA for mental health interventions in intellectual and developmental disabilities in February 2022 to compare EASE to the Unified Protocol in ten community clinics. We were invited to submit a full proposal in early March and submitted that proposal at the beginning of May 2022 (funding decisions announced in December 2022).
- The EASE co-authors are also considering additional funding options
- Researchers and trainees at both study sites are regularly discussing research ideas for baseline data as we await study completion.

\* The SOW originally stopped recruitment at month 36, eligibility testing at month 39, and therapy sessions in month 44, however we have sought no cost extension to continue recruitment as funds allow. Recruitment has stopped at month 44, eligibility stopped at month 45, therapy sessions are now expected to end in month 53, and 3-month follow-ups will be completed in month 56.

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

*If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.*

Nothing to report.

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

*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.*

#### **Scientific and Community Presentations:**

- White, S. W. (November 2021). Helping teenagers to regulate strong emotions. *International Autism Congress*. Turkey.
- Beck, KB. (December 2021). Mindfulness-based Interventions for Autism Spectrum Disorder. *Leadership Education in Neurodevelopmental Disabilities and Related Disorders (LEND Program) Seminar*. University of Pittsburgh, Pittsburgh, PA
- Beck, KB (December 2021). Mindfulness-based interventions. *Invited lecture, Clinical Applications in Counseling course*. University of Pittsburgh, Pittsburgh, PA
- Mazefsky, Carla (March 2022). Emotion dysregulation in ASD: What We Have Learned and Where We Need to Go. Child Psychology Seminar at King's College, London, UK.
- Mazefsky, Carla (March 2022). Emotion dysregulation in ASD: Why it Matters and What We are Doing About It. Simons Foundation Powering Autism Research Knowledge (SPARK) Webinar.
- o **2,600 views to date on YouTube in addition to record number of live attendees.**
- Beck, Kelly. (March 2022). Provided lecture "Mindfulness-based interventions for Occupational Therapists", Pitt Occupational Therapy OTD, 2 hours
- Beck, Kelly (April 2022). Evidence-based mindfulness interventions for neurodivergent individuals. Oral breakout session presentation at the Pennsylvania Rehabilitation Association Annual Professional Development Institute. Summerdale, PA.
- Beck, Kelly (April 2022). Provided lecture "Mindfulness-based interventions for social workers", Pitt School of Social Work, 1.5 hours
- Beck KB\*, Northrup JB\*, Breitenfeldt KE, Porton S, Day TN, MacKenzie KT, Conner CM, Mazefsky CA (May 2022). Community-informed development and pilot of the Emotion and Awareness Skills Enhancement team-based program (EASE-Teams). International Society for Autism Research. Austin, Texas. \*Joint first author
- Antezana L, Conner CM, Peven JC, Beck KB, White SW, Mazefsky CA (June 2022). Executive Functioning difficulties are associated with emotion dysregulation in autistic adolescents and adults. University of Pittsburgh Department of Psychiatry Research Day. Pittsburgh, Pennsylvania.

**Written Products/Press:** n/a

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

*If this is the final report, state “Nothing to Report.”*

*Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

As we enter a no-cost extension period, we will continue midpoint, endpoint, and follow-up assessments and EASE and ACC treatments, offering telehealth options as needed and requested. We will also continue to follow the guidance of states, institutions, and the DoD concerning in-person contact with participants for therapy sessions and testing. We will also continue to hold regular supervisor of clinicians and study assessors, conduct data cleaning, data transformation, data analyses, prepare for the main outcomes paper, create a newsletter of results for participants and dissemination materials, and continue to create clinician training materials and update our manual for future dissemination and implementation of EASE into community settings.

**4. IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

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

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).*

Nothing to report.

*Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.*

Nothing to report.

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

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:*

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report.

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

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:*

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

- 5. CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:*

**Changes in approach and reasons for change**

*Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.*

Nothing to Report.

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

*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

During the seventh quarter of this project, the COVID-19 pandemic began to affect the United States. We transitioned all participant activities online from March-August 2020, and have operated in a hybrid in-person/telehealth model since August 2020. We will make future decisions regarding in person assessment and sessions in collaboration with our department, IRB, and DoD.

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

*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

Nothing to report- no significant changes that impacted expenditures.

**select agents**

*Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.*

**Significant changes in use or care of human subjects**

No significant changes to report in the care of human subjects.

**Significant changes in use or care of vertebrate animals**

Not applicable.

**Significant changes in use of biohazards and/or select agents**

Not applicable.

**6. PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

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

*Report only the major publication(s) resulting from the work under this award.*

**Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

% Beck KB<sup>^</sup>, Northrup JB<sup>^</sup>, Breitenfeldt KE, Porton S, Day TN, MacKenzie KT, Conner CM, Mazefsky CA (2022). Stakeholder informed development of the Emotion Awareness and Skills Enhancement team-based program (EASE-Teams). *Autism*. 2022 Apr; 26 (3): 586-600.  
doi: 10.1177/13623613211061936. PMID: 34903083. <sup>^</sup>=joint first author

Beck KB<sup>^</sup>, Kulzer J<sup>^</sup>, Trabert C, Meyer EC, Colacci J, Pramuka M, McCue M. (in press, 2022). A vocational rehabilitation partnership to provide transition services to young adults with neurodevelopmental disabilities: The Cognitive Skills Enhancement Program. *Journal of Vocational Rehabilitation* <sup>^</sup>=joint first author

% Susam BT, Riek NT, Beck K, Eldeeb S, Yun J, Hudac CM, Gable P, Conner C, Akcakaya M, White S, Mazefsky CA (2022). Quantitative EEG changes in Youth with ASD following brief mindfulness meditation exercise. *IEEE Trans. Neural Syst. Rehabilitation Eng*. In press.  
doi: 10.1109/TNSRE.2022.3199151

% Products created with data from HRSA-AIR-P grant to adapt EASE for individuals with ASD and co-occurring intellectual disability, or from a NSF CAREER award to use EEG to measure changes in emotion dysregulation in ASD. While from different grants, these products would not have been possible without DoD funding and the original EASE program that is the focus of this DOD award. The DOD award is also cited as a funding support for these products.

**Books or other non-periodical, one-time publications.** Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

N/A

**Other publications, conference papers and presentations.** Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.

Mazefsky C, Beck K, Conner C, White SW. The Emotion Awareness and Skills Enhancement (EASE) Program: A Mindfulness-Based Intervention for Adolescents and Young Adults with Autism Spectrum Disorder. In *Transdiagnostic Applications and Targets of Mindfulness Interventions in Youth* (D. Hafeman, Chair), Symposium. American Academy of Child and Adolescent Psychiatry Annual Meeting. 2021 Oct. Atlanta, GA

% Conner, C.M., chair. (2021, November). Clinical roundtable: Adapting Interventions for Individuals with Intellectual Disability: Considerations and Challenges. Association of Behavioral and Cognitive Therapies Annual Convention; November 2021. New Orleans, Louisiana.

% Beck KB\*, Northrup JB\*, Breitenfeldt KE, Porton S, Day TN, MacKenzie KT, Conner CM, Mazefsky CA (May 2022). Community-informed development and pilot of the Emotion and Awareness Skills Enhancement team-based program (EASE-Teams). International Society for Autism Research. Austin, Texas. \*Joint first author

Antezana L, Conner CM, Peven JC, Beck KB, White SW, Mazefsky CA (June 2022). Executive Functioning difficulties are associated with emotion dysregulation in autistic adolescents and adults. University of Pittsburgh Department of Psychiatry Research Day. Pittsburgh, Pennsylvania.

% Products created with data from HRSA-AIR-P grant to adapt EASE for individuals with ASD and co-occurring intellectual disability, or from a NSF CAREER award to use EEG to measure changes in emotion dysregulation in ASD. While from different grants, these products would not have been possible without DoD funding and the original EASE program that is the focus of this DOD award. The DOD support was acknowledged for all of the above.

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

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to report.

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

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- data or databases;
- physical collections;
- audio or video products;
- software;
- models;
- educational aids or curricula;
- instruments or equipment;
- research material (e.g., Germplasm; cell lines, DNA probes, animal models);
- clinical interventions;
- new business creation; and
- other.

Nothing to report.

- **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

**What individuals have worked on the project?**

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change”.

Example:

Name: Mary Smith  
Project Role: Graduate Student  
Researcher Identifier (e.g. ORCID ID): 1234567  
Nearest person month worked: 5

Contribution to Project: Ms. Smith has performed work in the area of combined error-control and constrained coding.

Funding Support: The Ford Foundation (Complete only if the funding support is provided from other than this award.)

University of Pittsburgh

Name: Carla Mazefsky  
**No change**

Name: Kelly Beck  
**No change**

Name: Caitlin Conner  
**No Change**

Name: Shannon Porton  
**No change**

Name: Michelle Perrin  
**No change**

Name: Annaliese Lausberg  
**No change**

Name: Hannah Maisel (left position on 9/10/21)  
Project Role: Independent rater  
Researcher Identifier (e.g., ORCID ID):  
Nearest person month worked: 1 calendar month  
Contribution to Project: She completed blind rater assessments.

Name: Cecilia Chi  
**No change**

Name: Jiebiao Wang  
**No change**

University of Alabama

Name: Susan White

**No change**

Name: Philip Gable

**No change**

Name: Nicole Powell

**No change**

Name: Shane Jones

**No change**

Name: Alexis Brewe (left position in August 2021)

Project Role: Project Manager

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 1.8 months

Contribution to Project: Ensuring subject access to WDX and eCoach, monitoring assessments and enrollment, coordinating staff training and supervision, study therapist

Name: Joshua Golt (started position in August 2021)

Project Role: Project Manager

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 1.8 months

Contribution to Project: Ensuring subject access to WDX and eCoach, monitoring assessments and enrollment, coordinating staff training and supervision, study therapist

**Pitt changes:**

- 1.) Hannah Maisel left her position in September 2021.

**UA changes:**

- 1.) Joshua Golt replaced Alexis Brewe as Project Manager in August 2021.

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

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The*

awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

**Other support changes:**

\* added

# removed

% percentage or year changed

**MAZEFSKY, CARLA A.**

**CURRENT** [amounts below adjusted to ensure sufficient effort available for pending projects]

<p><b>%D ARI70202 (Mazefsky)</b>          Department of Defense          A Randomized Controlled Trial of the Emotion Awareness and Skills Enhancement (EASE) Program for ASD          To formally evaluate efficacy of EASE via a sufficiently powered, two-site randomized-controlled trial (RCT).  <b>(Akcakaya)</b>          NSF          CAREER: Towards a Biologically Informed Intervention for Emotionally Dysregulated Adolescents and Adults with ASD          To develop robust electroencephalography (EEG)-based brain computer interface (BCI) systems integrated in virtual/augmented reality environments that can be used by individuals with ASD, especially as emotion regulation (ER) intervention tools.</p>	<p><b>8/1/2018 - 7/31/2023</b></p>	<p><b>0.60</b></p>
<p><b>%D (renewal) AIC Phase 4 (Siegel)</b>          SIMONS          The Autism Inpatient Collection Phase 4          To refine and validate physiological biomarkers of imminent aggression risk.          Sponsor Grants Officer: Richard McFarland;          Simons Foundation,          160 Fifth Avenue,          New York, NY, 10010</p>	<p><b>12/1/2021-11/1/2022</b></p>	<p><b>0.9</b></p>
<p><b>%D 5 R01 HD079512-07 (Mazefsky)</b>          NICHD          Change-Sensitive Measurement of Emotion Dysregulation in ASD Across the Lifespan          To build on the EDI's conceptual and psychometric strengths and apply Patient-Reported Outcomes Measurement Information System (PROMIS®) methods to develop the EDI-Young Child (EDI-YC for ages 2-5) and the EDI Self-Report (EDI-SR for ages 12+).          Grants Management Specialist: Saiyda Khan, NICHD          6710B Rockledge Drive, Room 3161A, MSC7004          Bethesda, MD 20817</p>	<p><b>5/4/2020 – 2/28/2025</b></p>	<p><b>2.25</b></p>
<p><b>%D (Mazefsky)</b>          Autism Speaks          Developing a Gold Standard for Tracking Adult Functional Outcomes in Autism Spectrum Disorder          To improve progress monitoring capabilities and support more informed adult transition policies for autism spectrum disorder by establishing the clinical utility of a new measure via evaluation of correlates with Medicaid claims and service use.</p>	<p><b>3/1/2020 - 2/28/2023</b></p>	<p><b>0.6</b></p>

**Other support changes:**

\* added

# removed

% percentage or year changed

**MAZEFSKY, CARLA A.**

**%D 1 R01 HD100392-01 (Mazefsky/Eack) 5/19/2020 - 2/28/2025 2.25**

NICHHD

Change-sensitive Measurement of Adult Functional Outcomes in Developmental Disabilities

To develop precise proxy and self-report measures of functional outcomes in employment, independent living, and social functioning for adults with intellectual and developmental disorders (IDD) that is change-sensitive for use in clinical trials.

**%D 5 R01 MH119172-02 (Foss-Feig) 8/6/2019 - 5/31/2024 0.12**

NIMH

PROMIS-Guided Development and Validation of a Dimensional Observer-Report Measure of Positive and Negative Features of ASD

To develop and validate a new measure of positive and negative symptoms in ASD.

**PENDING**

**\*1 P50 MH130957-01 (Overall PI: Mazefsky) 07/2022- 06/2027 1.2**

NIMH

Mental Health in Autistic Adults: An RDoC Approach (Project 1: Neuroimaging of Emotional Reactivity in Autistic Adults)

To quantify how autistic and non-autistic individuals continue to experience the effects of a stimulus after it is removed, allowing us to contrast neural reactivity to other indicators of subsequent reactivity.

**\*1 P50 MH130957-01 (Overall PI: Mazefsky) 07/2022- 06/2027 0.6**

NIMH

Mental Health in Autistic Adults: An RDoC Approach (Project 3: Daily Life Emotion Dysregulation in Autistic Adults with Ambulatory Psychophysiology)

To characterize how ED emerges in a variety of contexts across response systems (i.e., subjective, behavior, physiology) in daily life.

**\*1 P50 MH130957-01 (Overall PI: Mazefsky) 07/2022- 06/2027 1.8**

NIMH

Mental

Health in Autistic Adults: An RDoC Approach (Administrative Core)

To provide organizational structure and support integration of the Cores and Research Projects.

**\*1 (Mazefsky/White) 03/2023- 02/2027 1.8**

PCORI

The Emotion Awareness and Skills Enhancement (EASE) Program versus the Unified Protocol (UP)

To conduct a comparative effectiveness RCT in which we compare a mindfulness-based intervention developed for autistic patients (EASE) to the Unified Protocol (UP), an established intervention rooted in cognitive behavioral therapy.

**Other support changes:**

\* added

# removed

% percentage or year changed

**WHITE, SUSAN W.**

\* **AR210169 (Shaffer/Co-I White)** **10/01/22-09/30/27** **1.05**

Department of Defense

Regulating Together: Randomized Controlled Trial Examining Predictors, Facilitators, and Barriers to Treatment Success in Emotion Dysregulation and ASD

This RCT will compare a novel group-based treatment (Regulating Together) to an active control condition to examine impact on emotion dysregulation and mental health symptoms in school-age children with ASD.

\* **(White)** **02/01/22-01/31/24** **0.1**

Organization for Autism Research

Improving Outcomes in Autism: Community Implementation of Stepped Transition in Education Program

This is a pilot feasibility trial to evaluate the impact of the STEPS program to support transition to adulthood for people diagnosed with ASD, as implemented by community providers.

\* **R21HD104164 (Gan/Co-I White)** **08/03/21-07/31/23** **0.125**

NICHD

(direct)

Assessing Children's Screen Time Exposure with a Wearable Sensor

This is a technology development study to investigate utility of a wearable sensor that will detect children's observation of screens within the natural environment.

**R61MH117192 (B. White/S. White)** **02/06/20 – 01/31/25** **0.45**

National Institute of Mental Health

(direct)

Facial Affect Sensitivity Training for Young Children with CU Traits

This study is funded via the R61R33 mechanism, and the goal is to determine if computerized attentional retraining can impact change in callous-unemotional traits in young children.

Grants Management Specialist: Theresa A. Mercogliano  
6001 Executive Blvd, NSC BG RM 6125  
Rockville, MD 20852

%D **R01MH114906 (Corbett/White)** **11/01/17 – 11/30/22** **0.08**

National Institute of Mental Health

Investigating Social Competence in Youth with Autism: A Multisite RCT

To determine the efficacy of SENSE Theatre training, against an active control intervention, in improving social competence, a three-site RCT to investigate the efficacy of a theatre-based intervention against an active control intervention. Specific aims are to evaluate efficacy and determine whether detected changes in face memory and social interaction are due to the SENSE Theatre treatment.

Sponsor grants officer: Theresa A. Mercogliano  
6001 Executive Blvd, NSC BG RM 6125  
Rockville, MD 20852

**Other support changes:**

\* added

# removed

% percentage or year changed

**WHITE, SUSAN W.**

**\*(Cox & Kois; Co-I: White)** **10/23/21-10/22/22** **0.0**  
Sozosei Foundation  
Establishing a Center for Research in Behavioral Health and the Criminal Legal System

This is seed funding to begin a new research center dedicated to improving mental and behavioral healthcare within the criminal justice system.

**W81XWH-18-0284 (Mazefsky)** **08/01/18-7/31/22** **0.45**  
Department of Defense  
A Randomized Controlled Trial of the Emotion Awareness and Skills Enhancement (EASE) Program for ASD

To formally evaluate efficacy of EASE via a sufficiently powered, two-site randomized-controlled trial (RCT).

**Alabama Life Research Institute (White)** **11/01/19-08/01/22** **0**  
School-Based Treatment for Emotional Reactivity: A Pilot Study

This is a pilot study of a school-based group intervention to utilize mindfulness to improve emotion dysregulation. The aim is to evaluate preliminary feasibility of a new mindfulness program.

**PENDING**

**\* MH128467 (White)** **TBD** **0.45**  
National Institute of Mental Health  
Optimizing CBT Implementation among Community Providers Through Internet-Based Consultation and Networking (I-CAN)

In this R21 study, my colleagues and I develop and evaluate a novel digital peer consultation platform designed to improve use of research-supported intervention strategies among community-based providers operating in low-resource, rural areas.

**Other support changes:**

\* added

# removed

% percentage or year changed

**CONNER, CAITLIN M.**

[Current efforts below were adjusted to provide room for pending projects]

**W81XWH-18-0284 (Mazefsky)** **08/01/18-7/31/22** **0.90**  
Department of Defense  
A Randomized Controlled Trial of the Emotion Awareness and Skills Enhancement (EASE) Program for ASD

To formally evaluate efficacy of EASE via a sufficiently powered, two-site randomized-controlled trial (RCT).

**(Akcakaya)** **2/15/2019 - 1/31/2024** **0.60**  
NSF  
CAREER: Towards a Biologically Informed Intervention for Emotionally Dysregulated Adolescents and Adults with ASD

Grants Management Contact: Irene Sattler ([isattler@nsf.gov](mailto:isattler@nsf.gov))

To develop robust electroencephalography (EEG)-based brain computer interface (BCI) systems integrated in virtual/augmented reality environments that can be used by individuals with ASD, especially as emotion regulation (ER) intervention tools.

**%I 5 R01 HD079512-06A1 (Mazefsky)** **5/4/2020 – 2/28/2025** **2.40**  
NICHD  
Change-Sensitive Measurement of Emotion Dysregulation in ASD

To build on the EDI's conceptual and psychometric strengths and apply Patient-Reported Outcomes Measurement Information System (PROMIS®) methods to develop the EDI-Young Child (EDI-YC for ages 2-5) and the EDI Self-Report (EDI-SR for ages 12+).

Grants Management Specialist: Saiyda Khan, NICHD  
6710B Rockledge Drive, Room 3161A, MSC7004  
Bethesda, MD 20817

**%I 5 R01 HD100392-01 (Mazefsky/Eack)** **5/19/2020 - 2/28/2025** **2.78**  
NICHD  
Change-sensitive Measurement of Adult Functional Outcomes in Developmental Disabilities

Grants Management Contact: Saiyda Khan ([khansa@mail.nih.gov](mailto:khansa@mail.nih.gov))

To develop precise proxy and self-report measures of functional outcomes in employment, independent living, and social functioning for adults with intellectual and developmental disorders (IDD) that is change-sensitive for use in clinical trials.

**%I (Mazefsky)** **3/1/2020 - 2/28/2023** **2.40**  
Autism Speaks  
Developing a Gold Standard for Tracking Adult Functional Outcomes in Autism Spectrum Disorder

Grants Management Contact: Joan New ([jnew@autismspeaks.org](mailto:jnew@autismspeaks.org))

To improve progress monitoring capabilities and support more informed adult transition policies for autism spectrum disorder by establishing the clinical utility of a new measure via evaluation of correlates with Medicaid claims and service use.

**Other support changes:**

\* **added**

# **removed**

% **percentage or year changed**

**CONNER, CAITLIN**

**(Handen)** **4/1/2021 - 3/31/2023** **0.12**  
HRSA  
Autism Learning Health Network

Grants Management Contact: Joan New ([jnew@autismspeaks.org](mailto:jnew@autismspeaks.org))

To participate in the transfer of critical network findings to practice settings that will result in improved care and access to care from individuals with ASD and other DD.

# **1 U19 AG068054-01 (Handen/Christian/Head)** **9/30/2020 - 8/31/2025** **1.20**  
NIA  
Alzheimer's Biomarker Consortium - Down Syndrome (ABC - DS) (Core C: Clinical (Field Site))

Grants Management Contact: Priscilla Garner ([garnerpr@mail.nih.gov](mailto:garnerpr@mail.nih.gov))

To provide participants with DS (and sibling controls), clinical data, and biological specimens to enable the goals of each project, which is to examine biomarkers of Alzheimer's Disease in Down Syndrome.

**PENDING**

\***1 P50 MH130957-01 (Overall PI: Mazefsky)** **07/2022- 06/2027** **1.8**  
NIMH  
Mental Health in Autistic Adults: An RDoC Approach (Project 1: Suicidality in Autistic Adults: Self-Report Development and Trajectories)

To develop a suicidality measure for autistic adults, the Autism Suicidality Inventory, that will capture a continuum of suicide risk.

\***1 P50 MH130957-01 (Overall PI: Mazefsky)** **07/2022- 06/2027** **1.2**  
NIMH  
Mental Health in Autistic Adults: An RDoC Approach (Project 2: Daily Life Emotion Dysregulation in Autistic Adults with Ambulatory Psychophysiology)

To characterize how ED emerges in a variety of contexts across response systems (i.e., subjective, behavior, physiology) in daily life.

\***1 P50 MH130957-01 (Overall PI: Mazefsky)** **07/2022- 06/2027** **0.6**  
NIMH  
Autistic Adults: An RDoC Approach (Clinical Core)

To organize the extensive recruitment effort to assure the Projects meet their targeted enrollments and complete their proposed studies, while assuring all the data mandated by the ACE funding mechanism is collected.

\***1 (Mazefsky/White)** **03/2023- 02/2027** **1.8**  
PCORI  
The Emotion Awareness and Skills Enhancement (EASE) Program versus the Unified Protocol (UP)

To conduct a comparative effectiveness RCT in which we compare a mindfulness-based intervention developed for autistic patients (EASE) to the Unified Protocol (UP), an established intervention rooted in cognitive behavioral therapy.

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

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*

*Provide the following information for each partnership:*

*Organization Name:*

*Location of Organization: (if foreign location list country)*

*Partner’s contribution to the project (identify one or more)*

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

Nothing to report.

• **SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:** *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.*

**QUAD CHARTS:** *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.*

- **APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*