

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

REPORT DATE: August 2020

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: 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		<i>Form Approved</i> <i>OMB No. 0704-0188</i>
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. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.		
1. REPORT DATE August 2020	2. REPORT TYPE Annual	3. DATES COVERED 1 Aug 2019-31 July 2020
4. TITLE AND SUBTITLE A Randomized Controlled Trial of the Emotion Awareness and Skills Enhancement (EASE) Program for ASD		5a. CONTRACT NUMBER
		5b. GRANT NUMBER W81XWH-18-1-0284
		5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S) Carla A. Mazefsky, Ph.D. E-Mail: mazefskyca@upmc.edu		5d. PROJECT NUMBER
		5e. TASK NUMBER
		5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Pittsburgh (Pitt) 3811 O'Hara St. Webster Hall, Suite 300 Pittsburgh, PA 15213		8. PERFORMING ORGANIZATION REPORT
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel 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

The **primary objective** of this study is to formally evaluate efficacy of the Emotion Awareness and Skills Enhancement (EASE) 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 2 of this four-year project above our projected recruitment targets, with 117 of 200 participants recruited, 71 participants screened, 60 enrolled, and 46 who have already completed the study.

15. SUBJECT TERMS

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

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER <i>(include area code)</i>
			UU	21	

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

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	1
2. Keywords	1
3. Accomplishments	1
4. Impact	4
5. Changes/Problems	5
6. Products	7
7. Participants & Other Collaborating Organizations	9
8. Special Reporting Requirements	17
9. Appendices	17

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 14-21) 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 seventh and eighth quarters were interrupted by the COVID-19 pandemic; however, we have adapted our procedures so that we can continue our project. The SOW listed the following goals for the second year of the project, and progress that has been made is listed below:

Task 1: Trial Infrastructure

- IRB renewed in December 2019
 - IRB amendments were approved to conduct therapy and assessment via telehealth and to adapt in-person participant visits for adherence to institutional standards for COVID-19 safety.
- HRPO approval obtained in October 2018
 - HRPO was alerted when we paused participant visits due to COVID-19, and 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.
- 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

- Ongoing recruitment since start of study; did press release at both universities, advertising in community websites and listservs, attended 2 community events, spoke at 5 events
- We continue to enroll new participants: Year 1-2 Number Recruited= 117; Number Screened= 71; Number Enrolled= 60; Number Completed= 46

Task 4: Therapy and Participant Evaluation

- Participants have gone through assessments for eligibility, pre-treatments, midpoints, post-treatments, and 3-month follow-ups at both sites and is ongoing. Since March 16th, 2020, we have obtained all pre-treatment, midpoint, post-treatment, and 3-month follow-ups online.
- 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.
- 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, staff audited the databases to ensure that timepoints are accurate and that scores are correctly calculated. Corrections were made as needed.

Task 5: Data analysis

- Co-Is have begun to analyze baseline scores, focused on ensuring whether randomization procedures are working as intended (see below)
- Analyses on Year 1-2 indicate no significant differences of randomization in age ($t_{(55)} = -0.67$; $p = 0.95$), gender ($t_{(52)} = -0.16$; $p = 0.87$), treatment site (UA or Pitt) ($t_{(55)} = 0.33$; $p = 0.87$), or EDI Reactivity score at baseline ($t_{(54)} = 1.00$; $p = 0.28$). Additionally, there are no significant site differences in age ($t_{(55)} = -0.95$; $p = 0.34$), gender ($t_{(68)} = -1.20$; $p = 0.24$), treatment randomization ($t_{(55)} = 0.33$; $p = 0.74$), or EDI-Reactivity score at baseline. ($t_{(55)} = -0.97$; $p = 0.34$)
- Direct assessment data has been cleaned following post double entry (not needed for direct entered questionnaire data into WDX)
- Analysis of study outcomes would be premature for Year 2 and thus have not yet occurred

Task 6: Dissemination and Transition

- Not applicable

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:

1. Mazefsky, Carla A. (October 2019). Assessment and Treatment of Emotion Dysregulation in Autism Spectrum Disorder. Invited talk for International Society of Autism Research Regional Meeting in Puerto Varas, Chile.
2. Conner, Caitlin M. (October 2019). Managing Emotion Dysregulation in ASD with Mindfulness. Invited talk at the Kennedy Krieger Institute's Center for Autism and Related Disorders Annual Autism Conference, Baltimore, MD.
3. Conner, Caitlin M. (October 2019). Emotion Dysregulation in ASD. Autism course in Psychiatry Residency Training Program, Year 2 Adult Psychiatry Residents, Pittsburgh, PA.
4. Mazefsky, Carla A. (January 2020). Assessment and Treatment of Emotion Dysregulation in Autism Spectrum Disorder. Invited Grand Rounds talk at the Stony Brook University Department of Psychology, Stony Brook, New York.
5. White, Susan W. (March 2020). *Can't Fight this Feeling: Emotion Regulation in Autism*. Invited Grand Rounds talk at the Marcus Autism Center, Atlanta, GA.
6. Shaffer, Rebecca, Mazefsky, Carla, & Conner, Caitlin. (March 2020). *Emotion Regulation in ASD Toolkit*. Autism Speaks Online Recording of Toolkit talk.

Written Products

1. EASE overview- updated in 2020 and distributed to interested researchers and clinicians on request.
2. Mindful about Meltdowns- PA Dept of Human Services handout using EASE techniques (March 2020) <https://paautism.org/resource/mindful-about-meltdowns/>

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

We are beginning to resume EASE and ACC therapy sessions, and modified eligibility appointments, in person with IRB-approved COVID-19 safety procedures. We have also been seeing EASE and ACC participants via telehealth, and will continue to offer this option to families. We will continue to follow the guidance of states, institutions, and the DoD concerning in-person contact with participants for therapy sessions and eligibility testing. In the meanwhile, our study will continue to adhere to the Statement of Work. We will be 1) continuing to recruit participants through local organizations, 2) scheduling participants for eligibility tests (our IRB has approved our COVID-19 safety plan and we have the ability to see participants both via telehealth and in person), 3) randomize participants, provide study therapies, and collect data, 4) continue to contact participants for their 3 month follow-up assessment, and 5) hold regular supervision of clinicians and study assessors. All of these tasks are already underway.

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.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “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. As of March 16, 2020, the University of Pittsburgh halted all in-person research projects and required all research staff to work remotely. We applied for and were granted IRB approval in late April to resume therapy and assessment sessions with currently enrolled participants via telehealth. Additionally, we applied and were granted IRB and institutional approval on 8/3/2020 to restart in-person appointments with COVID safety procedures in place. 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.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or 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, Conner CM, Breitenfeldt KE, Northrup JB, White SW, Mazefsky CA. Assessment and Treatment of Emotion Regulation Impairment in Autism Spectrum Disorder Across the Lifespan: Current State of the Science and Future Directions. *Child Adolesc Psychiatr Clin N Am.* 2020 Apr 3. doi: 10.1016/j.chc.2020.02.003. [Epub ahead of print]. Acknowledgement of federal support: yes.

White SW, Conner CM, Beck KB, Mazefsky CA. Clinical Update: the Implementation of Evidence-Based Emotion Regulation Treatment for Youth with Autism. *Evidence-Based Child and Adolescent Mental Health.* 2020 May [Epub ahead of print]. doi:10.1080/23794925.2020.1796551 Acknowledgement of federal support: yes

Beck KB, Conner CM, White SW, Mazefsky CA. Mindfulness 'Here and Now': Strategies for Helping Adolescents with Autism. *J. Am. Acad. Child Adolesc. Psychiatry.* (2020) [In press]. Acknowledgement of federal support: yes

Brewe AM, Mazefsky CA, White SW. (2020). Therapeutic alliance formation for adolescents and young adults with autism: Relation to treatment outcomes and client characteristics. *Journal of Autism and Developmental Disorders.* 2020 July [Epub ahead of print]. doi:10.1007/s10803-020-04623-z. Acknowledgement of federal support: yes

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).*

Mazefsky C.A., White S.W., Conner C.M., Beck, K.B. 2020. The Emotion Awareness and Skills Enhancement (EASE) Program. In: Volkmar F. (eds) *Encyclopedia of Autism Spectrum Disorders – Second Edition.* Springer, New York, NY.
<https://doi.org/10.1007/978-1-4614-6435-8>

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.*

1. *Brewer, Alexis, Mazefsky, Carla, White, Susan (November 2019). Therapeutic alliance and its relationship to treatment outcomes in autism. Poster presented at the Association for Behavior and Cognitive Therapy. Atlanta, GA.
2. Susam B, Mohamed S, Conner CM, Golt J, Porton S, Akcakaya M, White SW, Mazefsky CA. EEG-Based Brain-Computer Interface (BCI) for Distress Identification for Individuals with ASD. International Society for Autism Research Annual Meeting; May 2020. Seattle, Washington (presented online).
3. Breitenfeldt KE, Conner CM, White SW, Mazefsky CA. Clinical Validation of the Emotion Dysregulation Inventory for Autism. International Society for Autism Research Annual Meeting; May 2020. Seattle, Washington. (presented online).
4. Susam BT, Mohamed S, Conner CM, Akcakaya M, Golt J, Porton S, White SW, Mazefsky CA. EEG-based brain-computer interface (BCI) for Distress identification for individuals with ASD. Poster session presented at the Brain Computer Interface Society; May 2020. Brussels, Belgium (presented online)

- **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.

7. 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 (**time decreased**)
Project Role: PI
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2.2 months
Contribution to Project: Supervision of study; Staff training and supervision;
Recruitment; IRB compliance and data integrity; Co-lead cross-site therapist supervision; Lead local supervision

Name: Kelly Beck
No change

Name: Caitlin Conner (**time decreased**)
Project Role: Co-I/Clinician
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1.2 months
Contribution to Project: Attend cross-site and local supervision; Study therapist; Assist in data analyses, organize edits to EASE clinician manual

Name: Shannon Porton (**role expanded**)
Project Role: Project Coordinator/Evaluator/Clinician/ADOS Examiner
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 9.8 months
Contribution to Project: Conduct eligibility assessments; Track enrollment; Assist in blind rater training and oversight; Conduct eligibility assessments; Attend cross-site and local supervision; Study therapist

Name: Michelle Perrin (**time added**)
Project Role: Recruitment/Participant Screening
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1 month
Contribution to Project: Manage referrals; Assist in recruitment

Name: Annaliese Lausberg
No change

Name: Hannah Maisel
No change

Name: Rob Seres (**removed**)
Project Role: Data manager
Nearest person month worked: 0 months
Contribution to Project: Database and WDX development and management

Name: Cecilia Chi (**added**)
Project Role: Data manager
Nearest person month worked: 1.9 months
Contribution to Project: Database and WDX development and management

University of Alabama

Name: Susan White
No change

Name: Philip Gable
No change

Name: Nicole Powell
No change

Name: Alexis Brewe
No change

Name: Ricardo A. Wilhelm
No change

Name: Shane Jones
No change

Pitt changes:

- 1.) Carla Mazefsky (Site PI) and Caitlin Conner (Co-I) decreased time on project, while Shannon Porton (Project Coordinator) increased time as she transitioned into current role as project coordinator and therapist. Rob Seres was replaced by Cecilia Chi for data management.

UA changes:

- 1.) none

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

%ARI70202 (Mazefsky)	8/1/2018 - 7/31/2022	1.20
Department of Defense	\$996,607	
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).		

%AIC Phase III (Siegel)	10/1/2018 - 9/30/2021	0.60
SIMONS	\$120,219	
The Autism Inpatient Collection Phase III		

To combine our multi-method assessment protocols with the goal of increasing aggression prediction

- accuracy by further refining our analytical methods, accounting for variability due to emotion regulation.

Sponsor Grants Officer: Marta Benedetti,
Simons Foundation,
160 Fifth Avenue,
New York, NY, 10010

* renewal from 5 R01 HD079512-05 (Mazefsky)

2 R01 HD079512-06A1 (Mazefsky)	5/4/2020 – 2/28/2025	1.20
NICHD	\$462,796	
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

# (Minshew/Mazefsky)	1/1/2014 - 6/30/2020	0.60
PA-HEAL	\$240,000	
Improving Function and Outcomes in Students with Autism Spectrum Disorder		

To develop a treatment to improve emotion regulation for verbal adolescents with ASD and to conduct a small open trial to determine acceptability, feasibility, and preliminary efficacy. Goals: 1) finalize the blended treatment manual, create ecoach website, and assemble all needed materials; 2) conduct a pilot study involving adolescents with ASD and emotion dysregulation at three sites to determine the feasibility of implementing the program, the acceptability of the program to adolescents and their families as evidenced by high attendance and satisfaction ratings, and fidelity to the treatment, e.g. that a trained therapist can follow the manual and implement EASE as intended by the developers.

Sponsor Contact: Morgan Williams – Fake
Health & Welfare Bldg;, 7th and Forster Streets, 2nd Flr West
Harrisburg, PA 17105

Other support changes:

* added

removed

% percentage or year changed

*** (Mazefsky)** **3/1/2020 - 2/28/2023** **1.20**
Autism Speaks \$227,271
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.

*** (Akcakaya)** **2/15/2019 - 1/31/2024** **1.00**
NSF \$46,141
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.

***1 R01 HD100392-01 (Mazefsky/Eack)** **5/19/2020 - 2/28/2025** **3.00**
NICHD \$426,598
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 changesensitive for use in clinical trials.

***(Kuhlthau)** **6/1/2019 - 8/31/2020** **1.20**
HRSA \$200,244
The Emotion Awareness and Skills Enhancement Program for Youth with ASD and Intellectual Disability (EASE-ID): A MindBody Intervention to Improve Sleep, Health, and Emotion Regulation

To extend the benefits of EASE to youth with ASD-ID and evaluate its impact on sleep and overall physical health.

***(Mazefsky)** **4/1/2019 - 3/31/2021** **0.60**
SIMONS \$9,278
Repeated ADOS Videos to Support Measure Development Initiatives

To establish a centralized, online collection of ADOS video-recordings, with associated demographic, diagnostic, medical, and genetic data.

***5 R01 MH119172-02 (Foss-Feig)** **8/6/2019 - 5/31/2024** **1.80**
NIMH \$136,519
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

Other support changes:

* added

removed

% percentage or year changed

WHITE, SUSAN W.

* R61MH117192 (B. White/S. White)	02/06/20 – 01/31/25	0.45
National Institute of Mental Health	\$1,284,376 (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

(Corbett/White)	11/01/17 – 10/31/21	1.23
National Institute of Mental Health	\$2,515,835	
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

W81XWH-18-0284 (Mazefsky)	08/01/18-7/31/22	0.45
Department of Defense	\$996,607	
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).

Other support changes:

* added

removed

% percentage or year changed

CONNER, CAITLIN M.

% W81XWH-18-0284 (Mazefsky) **08/01/18-7/31/22** **1.20**
Department of Defense \$996,607
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).

*** renewal from 5 R01 HD079512-05 (Mazefsky)**
2 R01 HD079512-06A1 (Mazefsky) **5/4/2020 – 2/28/2025** **1.20**
NICHD \$462,796
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

(Minshew/Mazefsky) **1/1/2014 - 6/30/2020** **0.60**
PA-HEAL \$240,000
Improving Function and Outcomes in Students with Autism Spectrum Disorder

To develop a treatment to improve emotion regulation for verbal adolescents with ASD and to conduct a small open trial to determine acceptability, feasibility, and preliminary efficacy. Goals: 1) finalize the blended treatment manual, create ecoach website, and assemble all needed materials; 2) conduct a pilot study involving adolescents with ASD and emotion dysregulation at three sites to determine the feasibility of implementing the program, the acceptability of the program to adolescents and their families as evidenced by high attendance and satisfaction ratings, and fidelity to the treatment, e.g. that a trained therapist can follow the manual and implement EASE as intended by the developers.

Sponsor Contact: Morgan Williams – Fake
Health & Welfare Bldg, 7th and Forster Streets, 2nd Flr West
Harrisburg, PA 17105

(Kuhlthau) **9/1/2015 - 8/31/2020** **0.60**
HRSA \$23,077
Autism Intervention Research Networks

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.

*** (Mazefsky)** **3/1/2020 - 2/28/2023** **0.60**
Autism Speaks \$227,271
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.

Other support changes:

* added

removed

% percentage or year changed

CONNER, CAITLIN

% Kuhlthau **6/1/2019 - 8/31/2020** **1.20**
HRSA \$200,244

The Emotion Awareness and Skills Enhancement Program for Youth with ASD and Intellectual Disability (EASE-ID): A MindBody Intervention to Improve Sleep, Health, and Emotion Regulation

To extend the benefits of EASE to youth with ASD-ID and evaluate its impact on sleep and overall physical health.

% reduced

Lubetsky **7/1/2016-6/30/2021** **1.20**
PA Department of Human Services \$1,880,000

ASERT (Autism Services, Education, Resources and Training Collaborative)

The ASERT Collaborative has been designed to bring together resources locally, regionally, and statewide. There are three ASERT regions (Western, Central, and Eastern) working together to streamline resources and share expertise across the Commonwealth. Each ASERT region is charged with understanding the needs of their respective region, including the needs of the most rural regions of the state and the most underserved populations. The mission of each of the ASERTs is to enhance the lives of Pennsylvanians with autism of all ages and abilities by improving regional access to quality services and interventions, providing information and support to families, training professionals in best practices and facilitating connections between individuals, families, professionals, and providers throughout the Commonwealth. Each ASERT serves as a valuable resource to BAS in supporting programs, which includes complex case consultation, program quality and improvement initiatives and data collection to inform program and policy development.

Sponsor Contact: Department of Human Services
Office of Developmental Programs
Bureau of Autism Services
P.O. Box 69183
Harrisburg, PA 17106

*** (Akcakaya)** **2/15/2019 - 1/31/2024** **1.20**
NSF \$46,141

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.

***1 R01 HD100392-01 (Mazefsky/Eack)** **5/19/2020 - 2/28/2025** **5.40**
NICHD \$426,598

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 changesensitive for use in clinical trials.

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.

8. 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.*

9. 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.*