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
Pittsburgh, PA 15213

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Fort Detrick, Maryland 21702-5012

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

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6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Pittsburgh
Pittsburgh, PA 15213-3320

8. PERFORMING ORGANIZATION REPORT

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

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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 1 of this four-year project above our projected recruitment targets, with 67 of 200 participants recruited, 45 participants screened, 43 enrolled, and 23 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**
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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 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.

There were no changes to the goals or direction of this project. The SOW listed the following goals for the first year of the project, and the following progress has been made:

Task 1: Trial Infrastructure

- Single site IRB approved at Pitt, renewed in January 2019; UA IRB ceded to Pitt
- HRPO approval obtained in October 2018
- eCoach, WDX, and databases updated and NDAR data tables made prior to months 4-6

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
- Assessor and treatment-naïve rater training and on-going reliability procedures were established by month 6
- Student RAs 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 materials (brochure, ads, website) updated with funding sources before month 3
- Ongoing recruitment since start of study; did press release at both universities, advertising in community websites and listservs, attended 5 community events, spoke at 7 events
- We continue to enroll new participants: Year 1 Number Recruited= 67; Number Screened= 45; Number Enrolled= 43; Number Completed= 23

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
- Treatment sessions have been conducted at both sites and the provision of study treatments is ongoing
- 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

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 indicate no significant differences of randomization in age ($t_{(41)} = 0.44$; $p= 0.66$), gender ($t_{(41)} = 0.76$; $p= 0.45$), treatment site (UA or Pitt) ($t_{(41)} = 0.24$; $p= 0.81$), or EDI Reactivity score at baseline ($t_{(40)} = 1.01$; $p= 0.32$). Additionally, there are no significant site differences in age ($t_{(64)} = 0.65$; $p= 0.52$), gender ($t_{(52)} = 0.62$; $p= 0.54$), or treatment randomization ($t_{(41)} = 0.24$; $p= 0.81$).
- 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 1 and thus have not yet occurred

Task 5: Data analysis (continued)

- 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 1 and thus have not yet occurred

Task 6: Dissemination and Transition

- Not yet 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. White, S. W. (February 2019). *Can't Fight This Feeling: Understanding and Remediating Anxiety in Teens with Autism*. Invited presentation at Vanderbilt University, Nashville, TN.
2. Mazefsky, C. A. (April 2019). *Assessment and Treatment of Emotion Dysregulation in Youth with Autism Spectrum Disorder*. Invited panel on Emotion Dysregulation in High-Risk Youth. Annual North American Society for the Study of Personality Disorders Conference, Pittsburgh, PA.
3. Mazefsky, C. A. (April 2019). *Emotion Dysregulation and Suicide in ASD.* Invited keynote talk at the Annual Autism Capstone, Pittsburgh, PA.
4. Mazefsky, C. A. (May 2019). Invited opening address at a special meeting of the Interagency Autism Coordinating Committee (IACC) on the topic "*Addressing the Mental Health Needs of People on the Autism Spectrum.*" National Institute of Health, Rockville, MD.
5. White, S. W. (May 2019). *Can't Fight this Feeling? So Stop Trying: Emotion Regulation in Autism.* Lecture at the Simpson-Ramsey Lectureship, Birmingham, AL.
6. Mazefsky, C. A. (July 2019). *Meeting the Needs of Clients with ASD and Neurodevelopmental Disorders: Adding Mindfulness and Other Modifications to Enhance CBT Effectiveness.* Invited Address at the World Congress of Behavioral and Cognitive Therapies, Berlin, Germany.

Scientific and Community Presentations (continued):

7. Conner, C. M. (July 2019). *REAACT Program*. Presented an overview of C. Mazefsky's lab projects at the ASERT Leadership Meeting to state Bureau of Autism Services staff, Pittsburgh, PA.

Written Products

1. EASE overview- distributed to interested researchers and clinicians on request.
2. EASE overview included in Autism Connection of PA Fall 2018 newsletter.
3. Emotion regulation/EASE overview included in ASERT July 2019 newsletter.

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

The plans for the next quarter follow the Statement of Work, which includes 1) continuing to recruit participants through local organizations, 2) schedule participants for eligibility tests, 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:** D*escribe 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.

***W*hat 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.

There are no anticipated problems.

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).*

  Nothing to report.

  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., White, S., & Conner, C. (in press). The Emotion Awareness and Skills Enhancement (EASE) Program. In F. R. Volkmar (Ed.), Encyclopedia of Autism Spectrum Disorders, Vol. 4. doi:10.1007/978-1-4614-6435-8_102186-1

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.

Nothing to report.

- **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.

- **Other Products**
  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*
No Change

Name: *Kelly Beck*
No change

Name: *Caitlin Conner*
No change

Name: *Joshua Golt*
Removed

Name: *Shannon Porton*
Project Role: *Project Coordinator/Evaluator/Clinician/ADOS Examiner*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *7.8 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; Study coordination; Oversee fidelity raters*

Name: *Michelle Perrin*
Project Role: *Recruitment/Participant Screening*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *2.4 months*
Contribution to Project *Manage referrals; Assist in recruitment*

Name: *Annaliese Lausberg*
No change

Name: *Rob Seres*
Removed

Name: *John Markiewicz*
Project Role: *Data Management*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *1.8 months*
Contribution to Project *Manage database, online questionnaires, and enrollment tracking; NDAR submissions*

University of Alabama

Name: *Susan White*
Project Role: *UA Site PI*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *1 month*
Contribution to Project: *Supervision of study at UA; Staff training and supervision; Recruitment; IRB compliance and data integrity; Co-lead cross-site therapist supervision; Lead local supervision*

Name: *Nicole Powell*
Project Role: *Co-Investigator*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *1 month*
Contribution to Project *Subject recruitment, ascertainment, and diagnostics; Obtain training and demonstrate reliability in administration of blind rater measures; Assign blind rater scores*

Name: *Alexis Brewe*
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: *Nicole Capriola-Hall*
Project Role: *Study therapist*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *3 months*
Contribution to Project: *Study therapist; Attend cross-site and local supervision*

Name: *Ricardo A. Wilhelm*
Project Role: *Evaluator*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *1.2 months*
Contribution to Project: *Assessment of emotion regulation*

Name: *Shane Jones*
Project Role: *Study therapist*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *1 month*
Contribution to Project *Lead recruiter; Study therapist; Attend cross-site and local supervision*

Pitt changes:

1.) Josh Golt (Project Coordinator; 1.9 months) departed his position in May 2018; Shannon Porton took over his coordinator duties in addition to her role as clinician/evaluator and Michelle Perrin took over administrative and screening duties. Rob Seres was replaced by JJ Markiewicz for data management (JJ has a long history of supporting the autism research program and has NDAR experience).

UA changes:

1.) White, Powell, and Jones' time was slightly decreased, and Gable and Brewe's time was increased to better represent their time spent on the project. No duties were changed.
2.) Wilhelm was added to conduct testing and Capriola-Hall was removed as a study therapist.

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

MAZEFSKY, CARLA A.

CURRENT

ARI70202 (Mazefsky) **8/1/2018 - 7/31/2022** **2.40**
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).

 # (Siegel) **10/1/2013 - 9/30/2018** **3.00**
Simons Foundation/Nancy Lurie Marks Family Foundation $103,892
Phenotyping of the Severely Affected Autism Population

To utilize an inpatient research network for children with ASD to evaluate new interventions and measures that will improve the lives of children with ASD. The specific aims of the network are to develop a comprehensive registry for the collection of clinical and biological data on severely affected children and adolescents with ASD, including the dimensions of communication ability, emotion regulation, aggression, self-injurious behavior, and intelligence, and examine the relationships among these factors.

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

***AIC Phase III (Siegel)** **10/1/2018 - 9/30/2021** **2.16**
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

Other support changes:
*** added**
 # removed

5 R01 HD079512-05 (Mazefsky) **9/10/2014 – 6/30/2020** **0.60**
NICHD $312,883
Change-Sensitive Measurement of Emotion Dysregulation in ASD

To refine and validate a new measure of emotional distress and emotion regulation for ASD, called the Emotion Dysregulation Inventory (EDI). Specific Aims: 1) Evaluate the dimensionality of the EDI and complete Item Response Theory (IRT) calibration. 2) Demonstrate the cross-sectional validity of the EDI 3) Establish That the EDI is sensitive to treatment change longitudinally.

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

5 R01 MH106450-04 (Eack) **6/1/2015 - 3/31/2020** **0.12**
NIMH $379,073
Cognitive Enhancement Therapy for Adult Autism Spectrum Disorder
To conduct a randomized-controlled efficacy trial of CET in 80 adults with ASD. Specific Aims: 1) evaluating The comparative effectiveness of CET versus EST on diverse cognitive and functional outcomes; 2) examining the impact of CET on fronto-temporal brain function and connectivity to elucidate the neural mechanisms of cognitive enhancement of this population and 3) using personal and neurobiological indicators to parse heterogeneity in treatment response and ide34ntify moderators indicative of individuals most likely to benefit from CET.

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

Other support changes:
*** added**
 # removed

WHITE, SUSAN W.

(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

 # R34 MH104337 (White) **09/01/14 – 07/31/18** (in NCE) **0.0**
National Institute of Mental Health $450,000
STEPS: Stepped Transition in Education Program for Students with ASD

To develop an empirically informed, school-based program to support students with ASD as they transition from secondary education to higher education (2 year and 4 year colleges). The purpose of this study is to finalize a novel transition support program and demonstrate feasibility of the new program.

Sponsor grants officer: Denise Juliano-Bult
6001 Executive Blvd., Rm 7144-MSC 9631
Bethesda, MD 20892-9631

 # R21/R33 MH100268 (White/Richey) **03/12/14 – 2/29/19** **1.0**
National Institute of Mental Health $1,338,059 (total costs)
Development of a Novel Neurotechnology to Promote Emotion Recognition in Autism

The goal of this project is to develop a real-time emotion recognition classification device to be used by adults with autism spectrum disorder, via integration of fMRI and EEG datastreams. Aims are to develop a real-time neurofeedback system of FER using a sample of adolescents and adults without ASD, and test the feasibility of an assistive technology that uses BCI to promote FER in a pilot controlled trial of adolescents and adults with ASD.

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

CONNER, CAITLIN M.

W81XWH-18-0284 (Mazefsky) **08/01/18-7/31/22** **2.40**
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).

5 R01 HD079512-05 (Mazefsky) **9/10/2014 – 6/30/2020** **0.60**
NICHD $312,883
Change-Sensitive Measurement of Emotion Dysregulation in ASD

To refine and validate a new measure of emotional distress and emotion regulation for ASD, called the Emotion Dysregulation Inventory (EDI). Specific Aims: 1) Evaluate the dimensionality of the EDI and complete Item Response Theory (IRT) calibration. 2) Demonstrate the cross-sectional validity of the EDI 3) Establish That the EDI is sensitive to treatment change longitudinally.

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

(Minshew/Mazefsky) **1/1/2014 - 6/30/2020** **2.40**
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 - 8/31/2019** **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.

* **(Kuhlthau)** **1/1/2019 - 8/31/2019** **1.20**
HRSA $102,584
Ameliorate Childhood Obesity Risk from Newer Antipsychotics for Individuals with Autism Spectrum Disorder (ACORN- ASD)

To adapt and pilot an empirically-validated pediatric weight management program (Healthy Habits for Life) within an existent site for the Autism Treatment Network for youth with ASD who gain weight on SGAs.

Other support changes:
*** added**
 # removed

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*** 3 U01 AG051406-04S6 (Handen/Klunk/Christian)** **9/30/2015 - 4/30/2020** **1.20**
NIA $323,319
Neurodegeneration in Aging Down Syndrome (NiAD): A Longitudinal Study of Cognition and Biomarkers of Alzheimer's Disease to examine progression of AD related biomarkers (Aß-, tau- and fluorodeoxyglucose-PET, structural and functional MRI, cerebrospinalfluid Aß and tau, plasma Aß and proteomics, genetics, neuropathology) and cognitive/functional measures.

(Lubetsky) **7/1/2016-6/30/2021** **3.0**
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

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.*