AWARD NUMBER: W81XWH-17-1-0634

TITLE: A Multidisciplinary Intervention for Encopresis in Children With ASD

PRINCIPAL INVESTIGATOR: Nathan Call, PhD, BCBA-D

CONTRACTING ORGANIZATION: Emory University

REPORT DATE: JANUARY 2023

TYPE OF REPORT: Final Technical Report

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
January 2023	Final	15SEPT2017 - 14SEPT2022

4. TITLE AND SUBTITLE

A Multidisciplinary Intervention for Encopresis in Children With ASD

5a. CONTRACT NUMBER
W81XWH-17-1-0634

5b. GRANT NUMBER
W81XWH-17-1-0634

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Call, Nathan, PhD, BCBA-D

E-Mail: nathan.call@choa.org

5d. PROJECT NUMBER
AR160059

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES
Nothing to report

14. ABSTRACT

Incontinence is a common concern among individuals with autism spectrum disorder (ASD). Existing treatments have generally utilized lengthy and invasive procedures and/or lacked methodological rigor. Furthermore, no treatment approach has incorporated medical approaches to address constipation, which is a significant contributor to encopresis in this population. In response to the absence of treatments for this problem, we designed a 2-week multidisciplinary intervention for encopresis (MIE) that combines medical and behavioral approaches. In MIE, a gastroenterologist assesses for and treats constipation. Patients also receive outpatient behavioral treatments that include structured sitting on a toilet to promote independent bowel movements. If one does not occur, the behavioral clinician administers a suppository and prompts the child to remain on the toilet. In doing so, continent bowel movements are predictably evoked, allowing for reinforcement. Eventually, the suppositories are gradually faded out to promote independence. The purpose of this study is to demonstrate the efficacy of MIE in a randomized controlled trial with 150 children with ASD.

15. SUBJECT TERMS
Autism Spectrum Disorder, Encopresis, Toileting, Clinical Trial

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
U	U	U	UU	19	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

1. INTRODUCTION:

Incontinence is a common concern among individuals with autism spectrum disorder (ASD). Existing treatments have generally utilized lengthy and invasive procedures and/or lacked methodological rigor. Furthermore, no treatment approach has incorporated medical approaches to address constipation, which is a significant contributor to encopresis in this population. In response to the absence of treatments for this problem, we designed a 2-week multidisciplinary intervention for encopresis (MIE) that combines medical and behavioral approaches. In MIE, a gastroenterologist assesses for and treats constipation. Patients also receive outpatient behavioral treatments that include structured sitting on a toilet to promote independent bowel movements. If one does not occur, the behavioral clinician administers a suppository and prompts the child to remain on the toilet. In doing so, continent bowel movements are predictably evoked, allowing for reinforcement. Eventually, the suppositories are gradually faded out to promote independence. The purpose of this study is to demonstrate the efficacy of MIE in a randomized controlled trial with 150 children with ASD.

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

Autism Spectrum Disorder, Encopresis, Toileting, Clinical Trial

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.

The major goal of this project was to demonstrate the efficacy of MIE. As described in the SOW, this study evaluated efficacy using three outcome measures: (1.1) rates of continence (defined as no more than one incontinent bowel movement and at least 6 continent bowel movements over 14 days) and toileting independence (defined as continent bowel movements without the use of medication for 80% of bowel movements over 14 days) 1-month after completing MIE; (1.2) long term outcomes (i.e., continence and independence 6 months post-treatment); and (1.3) improvement in collateral consequences of continence (e.g., stigma, exclusion, financial burden), as measured by the Parent Target Problem and CGI 6 months after treatment. Participants were randomly assigned to receive MIE or treatment as usual (TAU), which consisted of current best practices (i.e., medical treatment of constipation and parent education and consultation on toilet training with a doctoral level behavioral clinician)

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.

During the course of this study, we successfully recruited what we believe is one of the largest prospective samples of children on the autism spectrum ever to participate in a treatment study focused on toilet training. Figure 1. depicts the overall results of screening, consenting, and recruitment efforts. We screened 244 potential participants. Of these, 59 did not pass the screening interview because they did not meet one or more eligibility criteria and an additional 53 declined further involvement in the study. The remaining 129 individuals consented to participation and were formally enrolled in the study. An additional 12 participants were excused from study participation during the subsequent characterization and baseline phase and prior to randomization for meeting other exclusionary criteria or inability to participate (e.g., schedule conflict or lack of transportation). The remaining 129 participants were randomized into one of the two treatment groups (MIE 1-Week; MIE 2-Week; or TAU). Of those participants who underwent randomization, 27 withdrew from the study or were lost to followup

Importantly, our sample was highly representative in terms of racial/ethnic diversity, with more non-white participants than white, a plurality of African American participants, and roughly equal proportions of Hispanic or Latino to not Hispanic or Latino (see Table 1).

Consistent with the prevalence of ASD, 78% of the sample was male and 22% female. The average age of participants was 7.1 years.

Figure 1. Summary of Study Screening and Randomization

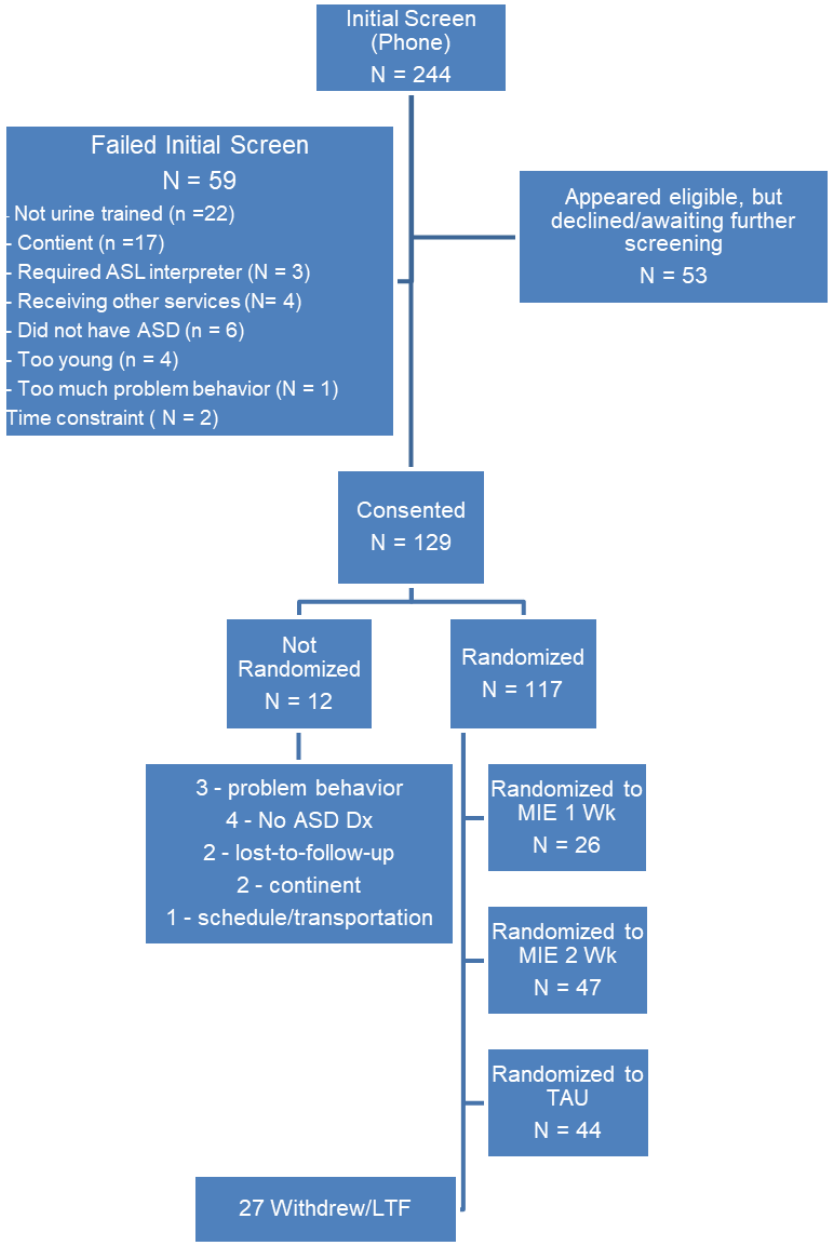

Table 1.

Characteristic	Randomized N = 117	Consented, not randomized N = 12
Age (years) Mean ± SD Median (Min, Max)	7.12 ± 1.76 6.75 (4.50, 12.5)	7.81 ± 1.66 7.83 (5.08, 10.3)
Gender		
Male	91 (77.8%)	7 (58.3%)
Female	26 (22.2%)	5 (41.7%)
Race		
Asian	4 (3.4%)	0 (0%)
Black/African American	58 (49.6%)	6 (50%)
Caucasian	43 (36.7%)	3 (25%)
Multiracial	9 (7.7%)	2 (16.7%)
Missing/Other	3 (2.6%)	1 (8.3%)

The COVID-19 pandemic caused slower than planned recruitment (See 5. Changes/Problems below), with the final participant enrolled at the end of October 2022. Because recruitment only recently finished, data cleaning and analysis are still underway. However, we are pleased to report that we have completed a preliminary analysis of one of our major outcome measures, the Clinical Global Impressions-Improvement (CGI-I) scale. Using this measure, participants who received a rating from a clinician blind to group assignment of “much improved” or “very much improved” were considered *responders*.

Overall, this measure showed significant differences in the percentage of participants categorized as responders between the three study groups at Endpoint (38.5% for MIE 1-Week vs. 44.7% for MIE 2-Week vs. 15.9% for TAU; p = .010; See Table 2). In addition, pairwise analyses demonstrated significant group differences in the percentage of responders between MIE 1-Week vs. TAU (p = .034) and MIE 2-Week vs. Tau (p = .003).

Importantly, these analyses approached missing data through imputation. In other words, consistent with an intent to treat approach, participants with missing data were treated as non-responders. However, we have identified the presence of a differential completion rate between groups, with more dropouts and participants lost to follow-up from the MIE 1-Week (27%) and MIE 2-Week (32%) groups compared to those randomized to TAU (7%). When participants who dropped out of the study or were lost to follow-up are excluded, response rates for both MIE 1-Week (52.6%) and MIE 2-Week (65.6%) increase, with little change in participants who completed TAU (17.1%). Overall differences between groups using these non-imputed results are again statistically significant in an overall comparison (p <.001) and in pairwise comparisons of MIE 1-Week vs. TAU (p = .005) and MIE 2-Week vs. TAU (p <.001). Thus, a conservative approach to study outcomes on this measure indicates significant differences between groups, but the larger differences between groups when omitting those who dropped out or were lost to followup indcate that participants who completed the course of treatment showed even greater improvements. It seems reasonable to ascribe the differential completion rate to the increased burden to completion inherent in the more intensive MIE. Thus, the increased response rate for participants who were able to complete MIE indicates that there is a need for future research to decrease this burden while maintaining positive outcomes.

We have not yet completed our analysis of the CGI-I at Follow-up (28 weeks). However, preliminary results suggest greater improvement on this measure compared to Endpoint. If confirmed, this result would be consistent with our conceptualization of MIE as an approach to overcoming barriers to successful toileting and establishing new skills in both the child and caregiver, followed by subsequent implementation at home to capitalize on those skills.

We have also not yet completed our analysis of other outcome measures, including the primary outcome measure of overall continence. We anticipate completing this analysis very soon after data cleaning is completed.

Table 2. Week-8 CGI by Groups overall, and pairwise for MIE vs. TAU

	MIE 1 Week N=26	MIE 2 Week N=47	TAU N=44	Overall P-Value	Pairwise 1-Wk vs. TAU P-Value	Pairwise 2-Wk vs. TAU P-Value
Imputed Non-Response						
Week 8 CGI						
No Response	16 (61.5%)	26 (55.3%)	37 (84.1%)	**0.010**	**0.034**	**0.003**
Response	10 (38.5%)	21 (44.7%)	7 (15.9%)			
Completers, N=92						
Week 8 CGI						
No Response	9 (47.4%)	11 (34.4%)	34 (82.9%)	**<0.001**	**0.005**	**<0.001**
Response	10 (52.6%)	21 (65.6%)	7 (17.1%)			

Adverse events were reviewed with participant's caregivers at baseline and every assessment visit (Weeks 4, 8, and 28) by an Independent Evaluator (IE). The IE inquired about the child's health complaints, medical visits and new medications, and several questions about daily activities (e.g., sleep, appetite, energy level, etc.) since the last study visit. New events (whether considered related to the treatment or not) were rated mild (present, but no intervention required) moderate (present, may be bothersome or may require intervention) or severe (present, bothersome and requires intervention). The IE also rated each adverse event as Definitely, Probably, Possibly, or Unlikely to be related to study participation, or Unrelated.

Caregivers reported a total of 377 events (see Table 3), with the majority classified as Mild (56%). There did not appear to be significant between group differences in the number of adverse events. No adverse events were categorized as being Definitely Related to study participation (see Table 5).

Table 3. Summary of Non-Serious Adverse Event Severity

AE Severity	MIE 1 Week N=26 (102 AEs)	MIE 2 Weeks N=47 (113 AEs)	TAU N=44 (162 AEs)	Total (N=377)
Mild	49 (48%)	69 (61.1%)	93 (57.4%)	211 (56%)
Moderate	48 (47.1%)	41 (36.3%)	67 (41.4%)	156 (41.4%)
Severe	5 (4.9%)	3 (2.6%)	2 (1.2%)	10 (2.6%)

Table 5. Summary of Non-Serious AE Relatedness

AE Severity	MIE 1 Week N=26 (102 AEs)	MIE 2 Weeks N=47 (113 AEs)	TAU N=44 (162 AEs)	Total (N=377)
Unrelated	95 (93.1%)	107 (94.7%)	143 (88.3%)	345 (91.5%)
Unlikely Related	2 (2%)	1 (0.9%)	12 (7.4%)	15 (4%)
Possibly Related	3 (2.9%)	3 (2.6%)	6 (3.7%)	12 (3.2%)
Probably Related	2 (2%)	2 (1.8%)	0 (0%)	4 (1%)
Definitely Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unknown	0 (0%)	0 (0%)	1 (0.6%)	1 (0.3%)

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.

The following individuals completed at least two months of training experience on this study, during which they engaged in the listed activities:

- Miles Call - Assisted in BM protocol, data collection, and administrative work (prepping for clients, filing, building folders).
- Sharon Daniel – Conducted BM protocol, data collection, graphed data, and administrative work (prepping for clients, filing, building folders).
- Mary Elmore Demott - Assisted in BM protocol, data collection, and administrative work (prepping for clients, filing, building folders).
- Daniel Hoban – Conducted BM protocol, data collection, graphed data, and administrative work (prepping for clients, filing, building folders).
- Carolyn Maynard – Conducted BM protocol, data collection, graphed data, and administrative work (prepping for clients, filing, building folders).
- Melanie Parks – Conducted BM protocol, data collection, made recruitment calls, and administrative work (prepping for clients, filing, building folders).
- Jamila Pitts – Conducted BM protocol, data collection, graphed data, and administrative work (prepping for clients, filing, building folders).
- Mikayla Ries – Conducted BM protocol, data collection, graphed data, and administrative work (prepping for clients, filing, building folders).
- Jordyn Saxton - Assisted in BM protocol, data collection, and administrative work (prepping for clients, filing, building folders
- Jazmin Simms – Assisted in BM protocol, data collection, and administrative work (prepping for clients, filing, building folders).
- Ashlynn Thompson – Conducted BM protocol, data collection, graphed data, and administrative work (prepping for clients, filing, building folders).

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.

Nothing to Report

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 described above, our most immediate task will be to complete the formal analyses of the outcome data. Based on preliminary analyses conducted to date we have identified five potential papers through which we plan to disseminate the following results:

- A main outcomes paper
- A paper characterizing children with ASD and comorbid encopresis, including the impact of encopresis on quality of life
- A paper detailing our use of telehealth to treat a subset of our sample as a result of the COVID-19 pandemic
- A paper describing secondary analyses, including constipation status as a moderator of treatment response

In addition, we have initiated conversations as a research team regarding a planned series of followup studies, beginning with a clinical trial of a comprehensive approach to addressing toileting issues in children and youth with ASD or other developmental disabilities (including a tiered approach to treating both encopresis and enuresis).

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).

To our knowledge this is the first RCT of a multidisciplinary treatment for any type of incontinence in children and adolescents with ASD. As such, it was necessary to develop a host of study procedures that have not previously been deployed. In addition, MIE relies upon a behavioral component based upon applied behavior analytic (ABA) methods. For largely philosophical reasons (e.g., historical emphasis on single subject methods) ABA-based approaches have rarely been studied in large RCTs. Furthermore, even in the few exceptions, large studies of ABA-based treatments have tended to focus on their use as comprehensive treatments for core features of ASD, with a few other larger studies of ABA-based treatments for challenging behavior such as aggression and self-injury. Thus, this study represents an expansion of the range of topics addressed within RCTs of ABA-based interventions to include incontinence. As such, we believe that this study will impact ABA providers by serving as an example of how ABA-based components can be studied as components within multidisciplinary treatments and within large RCTs.

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.

Although the behavioral component of MIE was a major element of treatment, it also included a medical component to identify and manage constipation. Thus, we expect that this study will also have an impact on medical providers who treat constipation in children and adolescents with constipation. To maximize this impact, we plan to submit the paper reporting our main outcomes to a high impact journal that reaches a wide audience of individuals providing care to individuals on the autism spectrum, including medical providers.

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.*

Results from this project may have an impact on policies relating to coverage for treatment of encopresis in children and adolescents with ASD and encopresis by payors and in practices related to the same. To maximize this impact, we have begun conversations related to future studies focused on implementation research that will examine uptake of this treatment approach.

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.

Statistical Power and Three Group Design As described in a memo submitted to Program Officer Dr. Stanley Niu (sent 10/17/19), we asked the unblinded statistician, Dr. McCracken, to prepare a report on enrollment and attrition for the Data Safety and Monitoring review of the study conducted on 10/14/19. In addition, although we did not request an interim analysis, we asked Dr. McCracken to examine the results on the Improvement subscale of the Clinical Global Impression (CGI-I) measure. We examined these results while remaining blinded to group assignment. Following the review, we agreed that the original study design warranted reconsideration.

Brief Background. The three-group design was proposed to extend our previous study findings by comparing the MIE 1-Week and MIE 2-Week groups- allowing each to be compared to TAU. Based on the large difference between the MIE 2-Week intervention and the control group in our pilot study, we proposed an unbalanced randomization: n=60 (MIE 2-Week); n=60 (MIE 1-Week); n= 30 (TAU). The larger samples in the two MIE groups were designed to achieve sufficient statistical power for this exploratory aim. Another important difference in the current study compared to our pilot study is the nature of the control condition. In the pilot study, the control condition was waitlist. By contrast, the control condition in the current study, Parent Education, is a more active condition.

Results of Data Safety and Monitoring Review. As noted, the statistician presented the response rates on the CGI-I without breaking the blind. The review of the first 52 participants revealed positive response rates ranging from 33% to 42% across the three groups. Although it was still early in the study, this blinded review indicated that our three-group design was unlikely to detect differences between groups. For example, these results suggested that the positive response rate in the Parent Education control group was greater than the 10% positive response rate in wait list control group in our pilot study.

Design Change. With the approval of Dr. Niu, and following approval of a protocol change by the Emory University IRB and HRPO, and given the exploratory nature of MIE 2-Week vs. MIE 1-Week comparison, we discontinued recruitment into the MIE 1-Week group and proceed with a two-group study (MIE 2-Week vs TAU) with balanced randomization going forward. This change increased the power of the two-group study. With the time remaining in the study, we enrolled 81 additional participants (n=35 in MIE 2-Week; n=46 TAU).

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.

Adaptations due to the COVID-19 Pandemic

The outbreak of the novel Coronavirus resulted in Emory University mandating discontinuation of all "non-essential" research activities on March 18th, 2020. To meet this requirement, we initially suspended enrollment of new participants. However, to ethically manage participants already enrolled we took the following steps:

1. One participant was actively receiving treatment at the time the guidance was delivered to enact social distancing and suspend non-essential research activity. The participant was in the crossover phase (originally randomized to TAU) and elected to discontinue treatment given concerns about COVID-19. For this participant we still collected endpoint measures within the already established visit windows even though they did not receive a full "dose" of the treatment.

2. Two participants were randomized shortly before discontinuation of study activities; one to TAU and one to MIE 2-Week. Our study team has experience delivering behavioral interventions via clinic-to-home telehealth, and so we submitted an amendment for the Emory University IRB to allow delivery of both MIE and TAU treatment via telehealth for these participants

3. We contacted the families of participants who were scheduled to attend a screening and consent visit to reschedule those appointments. We closely monitored our institution's guidance regarding when non-essential research activities could recommence, canceling schedule consents and treatment appointments one week at a time.

Once we had successfully addressed the immediate needs to pause the study, our focus shifted to the safe resumption of research activities. We were able to do this through adoption of a host of safety procedures, including the use of personal protective equipment, social distancing, screening procedures for anyone entering our facility, cleaning procedures, and shifting some study procedures to telehealth. On July 20th, 2020, we received approval from Emory University to recommence study activities. Prior to that, all study personnel had to undergo training on social distancing policies, and we obtained adequate personal protection equipment (PPE). As a result, we enrolled the first participant since the cessation of research activities due to COVID on 7/20/20.

Although we were able to recommence enrollment in the study at that time, enrollment continued at a slightly reduced rate from our pre-pandemic levels, in part due to a) hesitancy by potentially eligible families to enroll their child in a treatment study during the pandemic, and b) higher than previously encountered absenteeism during the treatment arm of the study resulting from families experiencing symptoms of COVID-19, screening positively for symptoms that required them to quarantine until they receive a negative test, or having to quarantine due to close contact with someone who tested positive for COVID-19.

The pause in recruitment and subsequent diminished rate of recruiting due to COVID-19 made it impossible for us to complete all enrollment and data analysis by the original study end date. Thus, we submitted a request for a no cost extension, which was approved August 11th of 2021.

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

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

Nothing to Report

Significant changes in use or care of vertebrate animals

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

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).*

Nothing to Report

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.*

Call, N. “Advancing Behavior Analysis by Extending the Continuum of Research Questions & Methods” Invited lecture delivered at the annual Thompson Center Autism Conference, St. Louis, MO (Sept. 26, 2019) and the Alabama Association for Behavior Analysis, Birmingham, AL (Oct. 10, 2019).

Muething, C. Treatment of Enuresis and Encopresis in Children with Autism Spectrum Disorder. Baylor University and Texas Children’s Hospital Grand Rounds, Houston, TX, 2021

Lomas Mevers,J., Lectureship: Toilet Training for Children with Developmental Disabilities, Tuberous Sclerosis Alliance, Sliver Springs, MD 2020

Lomas Mevers,J., Workshop: Toilet Training for Children with Developmental Disabilities, Tuberous Sclerosis Alliance, Sliver Springs, MD 2020

Lomas Mevers, J., Toilet Training individuals with Developmental Disabilities, Online Conference, Focus 34th Annual Educational Conference, 2021 (Invited Workshop)

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".

<u>Example:</u>

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.)*

No Change

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.

Nothing to Report

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://ebrap.org/eBRAP/public/index.htm*** *for each unique award.*

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

Nothing to Report

9. APPENDICIES: *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.*

Nothing to Report