

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
OFFICE OF GRANT & CONT ACCTNG 201 DOWMAN DR
ATLANTA GA 30322-1007

REPORT DATE: October 2021

TYPE OF REPORT: Annual Technical Report

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

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

Form Approved
OMB No. 0704-0188

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 October 2021		2. REPORT TYPE Annual		3. DATES COVERED 15SEPT2020 - 14SEPT2021	
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; Rock, Chelsea, BS E-Mail: nathan.call@choa.org chelsea.rock@choa.org				5d. PROJECT NUMBER AR160059	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) EMORY UNIVERSITY OFFICE OF GRANT & CONT ACCTNG 201 DOWMAN DR ATLANTA GA 30322-1007				8. PERFORMING ORGANIZATION REPORT NUMBER None	
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) eIRB	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S) None	
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. 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, 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 Unclassified	18. NUMBER OF PAGES 8	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Overall Project Summary	4
4. Key Research Accomplishments	6
5. Conclusion	6
6. Publications, Abstracts, and Presentations	6
7. Inventions, Patents and Licenses	6
8. Reportable Outcomes	6
9. Other Achievements	6
10. References	6
11. Appendices	7

1. INTRODUCTION:

Incontinence is a common concern among individuals with autism spectrum disorder. 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, 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:

Autism Spectrum Disorder, Encopresis, Toileting, Clinical Trial

3. OVERALL PROJECT SUMMARY:

The following Major Tasks were completed in this year of the grant:

- Randomization of the 99th subject (as of 9/29/2021)
- Completed DSMP meeting and report as scheduled (September, 2021)

Cumulative progress towards recruitment targets to date:

- a. Phone Screens completed – 213
- b. Participants Consented – 110
- c. Participants who failed screening - 7
- d. Participants Randomized – 99
- e. Presumed eligible participants who declined to enter – 1
- f. Participants withdrawn/dropped out AFTER randomization – 20
- g. Participants still in screening phase – 0

Table 1. Timeline and Milestones	Timeline
Major Task 2: Active Enrollment	Months
Continue Enrollment	36-45
Milestone: Randomize at least 100 subjects	38
Unblinded statistician & PI evaluate adverse events	36

Changes

Our prior annual report documented a host of changes that were implemented to address health and safety of participants and study personnel due to the coronavirus. Fortunately, those changes were sufficient, and we have not had to adopt any additional changes to our protocol over the past year of this reporting period.

Personnel

The only substantive change in personnel during this year of the study was the departure of Ansley Reich, lead research coordinator for this project. Mrs. Reich has transitioned to her new role at Marcus Autism Center. The fact that she remained within our center has made this transition a gentle one, as she is still able to provide consultation to her replacement, Chelsea Rock.

Problems

In our prior annual report, we documented the ways in which the outbreak of the novel coronavirus disrupted this study. Specifically, we were unable to enroll new participants or complete study procedures with participants already enrolled. In the current year of this study, our focus has been on resumption of research activities, including enrollment of new participants and execution of the study protocol. As described in our quarterly reports, 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. Through these efforts we were successfully able to resume research activities on this study shortly before our previous annual report. As a result, our study is back underway and recruiting 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 this 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 require them to quarantine until they receive a negative test, or having to quarantine due to close contact with someone who tests positively for COVID-19.

Although we are generally pleased with the progress made towards our study aims in this year, the pause in recruitment 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 this year. As a result, the end date of this study has been extended to 9/14/2022. We have evaluated our current trend for enrollment and can report that maintenance of our current enrollment rate would mean that we will achieve our enrollment targets within the period of the no-cost extension while still leaving adequate time for any participants randomized to the control group to cross over and receive the treatment protocol, as well as to conduct data analysis.

The change in end date resulted from the approval of the no-cost extension has also cause us to postpone our plan to conduct a practice export of data from our database to SAS, as listed in our original Scope of Work. We will now conduct this practice export of data in the upcoming year instead.

Participants

Over the previous year, 22 additional parents of have consented to enroll their child into the study, for a cumulative total of 110. Of these, 1 (a total of 7 to date) failed the in-person screen

4. KEY RESEARCH ACCOMPLISHMENTS:

Nothing to report

5. CONCLUSION:

After diligently working through challenges related to recommencing research activities and implementation of the study protocol, we successfully began enrolling participants, and continued to do so over the course of the reporting period. The delays caused by the pandemic, and its impact on the pace of enrolling new participants, caused us to miss recruitment targets for the project. However, we have submitted a no-cost extension request, which was approved, and our analysis indicates that continued recruitment at our current pace will allow us to complete the project by the new end date.

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

- (1) Lay Press: None
- (2) Peer-Reviewed Scientific Journals: None
- (3) Invited Articles: None
- (4) Abstracts: None

- a. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

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)

7. INVENTIONS, PATENTS AND LICENSES:

Nothing to report

8. REPORTABLE OUTCOMES:

Nothing to report

9. OTHER ACHIEVEMENTS:

Nothing to report

10. REFERENCES:

Nothing to report

11. APPENDICES:

Nothing to Report

TRAINING OR FELLOWSHIP AWARDS:

- Jamila Pitts – 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).
- Jazmin Simms – Assisted in BM protocol, data collection, 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).
- Mary Elmore Demott - Assisted in BM protocol, data collection, 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).
- Carolyn Maynard – Conducted BM protocol, data collection, graphed data, 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).
- Daniel Hoban – Conducted BM protocol, data collection, graphed data, 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).
- Kathryn Reisner – Entered data into database and administrative work (prepping for clients, filing, building folders).
- Sydney Hunter – Entered data into database and administrative work (prepping for clients, filing, building folders).
- Jessica Solomon – Assisted in BM protocol, entered data into database and administrative work (prepping for clients, filing, building folders).
- Vivian Muhumuza – Assisted in BM protocol, entered data into database and administrative work (prepping for clients, filing, building folders).

COLLABORATIVE AWARDS:

Nothing to Report

MARKING OF PROPRIETARY INFORMATION:

Nothing to Report