Informed Consent Form

Title: A Multidisciplinary Approach to the Treatment of Encopresis in Children with Autism Spectrum Disorders

NCT Number: NCT03197922

Date of IRB Approval: April 11, 2022

Encopresis Consent

Record ID _____

Thank you for your interest in participating in the encopresis (bowel movement accident) study at the Marcus Autism Center! The consent document is outlined in this link below.

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You are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University and Children's Healthcare of Atlanta
Consent to be a Research Subject and HIPAA Authorization

Title: A Multidisciplinary Approach to the Treatment of Encopresis in Children with Autism Spectrum Disorders
Principal Investigator: Nathan Call, PhD
Study-Supporter: Department of Defense

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

Please carefully read this form or have it read to you Please listen to the study doctor or study staff explain the study to you Please ask questions about anything that is not clear You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You may search this Web site at any time.

What is the purpose of this study?

This purpose of this study is to evaluate how effective a multidisciplinary intervention for encopresis (MIE) is for helping children with autism spectrum (ASD) not have bowel movement accidents. There are two groups in the study. One group will receive an intervention that consists of both medical and behavioral components. The medical part includes the use of a glycerin suppository, which is an over the counter (OTC) medication that increases the chances of a bowel movement while the child is on the toilet. The behavioral component is giving your child some of their favorite things for having a bowel movement on the toilet. The other group is our treatment as usual group (TAU). Children randomized to this group will have a two hour appointment with a Doctoral Level Psychologist to learn about procedures that parents can do at home to increases the chances of their child having a bowel movement in the toilet.

About 112 children with ASD and BM accidents will participate in this study at the Marcus Autism Center over four years.

What will I be asked to do?

Characterization and Medical Screening: This first visit involves tests for ASD, IQ, and daily living skills. Your child will also be screened by a pediatric gastroenterologist and assessed and treated for any constipation or other potential medical complications. These assessments and the medical screening will determine if your child is a good fit for the study. You will have some forms and questionnaires to complete, and you will also be trained to collect data on you're the frequency and type of your child's bowel movements at home. You will share this data with our study team either by email or by completing an online form.

After your child is deemed eligible for the study, he or she will be randomly assigned to one of two groups. The research team has no input on random assignment. It is done by a computer program. Your child has an equal chance of being put into the MIE group or the TAU group. Children who complete the TAU group will then be offered MIE. All groups will last 28 weeks. If your child is assigned to the MIE group, your child may be asked to stop taking any medications they currently take for BMs or constipation.

The two groups are:

MIE for two weeks. TAU, which involves one 2-hour session on toileting with a clinician but no medication. Baseline Visit: This visit will occur within 14 days of the characterization and medical screening visit. This appointment will involve you answering some questions and filling out some forms. On this day, your child will begin treatment if assigned to the MIE group or either you will have your TAU appointment.

Multidisciplinary Intervention for Encopresis (MIE): Children in the two-week MIE group will come to the Marcus Autism Center every business day (5 days/week) for appointments that last up to 3 hours. These appointments consist of a series of sitting routines (i.e., "sits"). Each sit consists of 10 minutes on the toilet, followed by 1 minute of standing, then repeating the 10 minutes on the toilet and 1 minute off, for 30 cumulative minutes of sitting. The first 30-minute sit is to provide your child with an opportunity for an independent continent bowel movement (BM). If your

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child has a bowel movement during this time, he will receive positive reinforcement (praise and a preferred toy or snack) and he may go home. If no continent bowel movement occurs, your child will get a 5-minute break and then a trained staff member will administer a dose of a liquid glycerin suppository, immediately followed by another 30-minute sit to ensure any resulting bowel movement is continent. If your child has a bowel movement during this time, he will receive positive reinforcement (praise and a preferred toy or snack) and he may go home. If your child does not have a BM during this sit, he will get a 30-minute break and will receive a second glycerin suppository. After the third sit the appointment ends even if a continent bowel movement did not occur. Glycerin suppositories are replaced by bisacodyl if 2 days pass without a continent bowel movement using the liquid glycerin suppository. As independent continent bowel movements begin to occur, the need for the medical regimen decreases, and is gradually faded out entirely. . A primary caregiver will also be trained on these techniques to use at home (see below). You will be given a handout that explains the suppositories in more detail.

Treatment As Usual (TAU): participants in the TAU group will receive an individual appointment lasting up to 2-hours in clinic with a doctoral level clinician with extensive experience in behavioral treatments for encopresis. This outpatient appointment will include a PowerPoint presentation and consultation regarding treatment of encopresis. During the appointment, the clinician will review strategies to increase continence. Specifically, the clinician will provide parent education on the following topics: how to collect and evaluate data on their child's bowel movements, how to establish and use a sit schedule, identifying behaviors that are precursors to bowel movements and how to use them to increase the probability of a bowel movement being continent, consequences for incontinence, and reinforcement for continence. In addition, participants in the TAU group will continue to implement any medical treatment for constipation as prescribed. Midpoint Visit: About 2 weeks after your baseline visit, you will have a Midpoint visit at the Marcus Autism Center that will involve some forms and outcome measures. After this visit, we will give you a 30-day supply of suppositories to utilize at home. We will also give you a treatment plan to do at home for either 4 or 5 weeks. You will also collect data on your child's BMs. We will call you twice during this time to collect the data.

Endpoint Visit: About 6 weeks after your baseline visit, you will have an Endpoint visit at the Marcus Autism Center that will involve some forms and outcome measures. After this visit, you will continue to implement the strategies at home for another 18 weeks but you will no longer be asked to collect data.

18-Week Home Implementation Phase: During this phase, the study team will call you once a month to remind you to continue to implement the intervention procedures and to confirm that you have an adequate supply of study medication. The study team will not provide any additional insight or clinical guidance because the goal of this phase is to determine the intervention's effectiveness. However, the study team may intervene clinically and terminate study participation if they feel that your child is in need of immediate emergency medical treatment.

After 17 weeks of you working with your child at home, we will call you and remind you to begin collecting data again on your child's BM for two weeks.

Follow Up Visit (Weeks 26-28): This visit will be similar to your past visits and last about an hour.

Part of treatment may involve physical management of your child, such as to address problem behavior (e.g., aggression, disruption, self injury) to ensure the safety of your child, yourself, and the therapist. Therapists are trained and will implement personal protective procedures (e.g., blocking hits, releasing grabs) if your child is aggressive (hurting others) to minimize any harm, prioritizing the safety of your child. In addition, the below procedures may be used as needed.

Prompting procedures: to gently guide your child to sit on the toilet, or to prompt him or her to engage in redressing or hygiene tasks. This may involve hand-over-hand physical guidance. Emergency restraint: If a researcher determines that your child cannot be kept safe by any other means, they will implement an emergency restraint procedure. This will be done only until it is deemed that your child is safe. If you are not there to observe the procedure, you will be notified by the researcher as soon as possible that this procedure occurred. A licensed psychologist is consulted for any restraint procedure used. Risks and Discomforts

There are risks and potential discomforts associated with this study. General risks include:

There is a chance for a breach of confidentiality. This means that someone who is not supposed to get your information does. We take many steps to prevent this from happening. Possible distress in your child. Some children become upset when separating from their caregiver. Some children also find the administration of the suppository to be uncomfortable and may become distressed as a result. We will take many steps to minimize this distress. If your child gets too upset we can take a break or end the visit. Some children experience abdominal discomfort from the suppositories. Possible distress for the parent. Your child's frustration can be stressful for a parent. If you get too uncomfortable, we can take a break or end the visit Bisacodyl Risks

The most common side effects of Bisacodyl are: pain, discomfort, diarrhea and inflammation Although uncommon, atony of colon may also occur where the colon loses muscle strength. This can cause constipation Irritation of the rectum may also occur Glycerin Risks

The most common side effects of Glycerin are: diarrhea, gas, nausea and cramps Rectal discomfort or a burning sensation may also occur You may withdraw your child from the study at any time and for any reason. We encourage you to talk with us about your concerns.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

This study is not designed to benefit you directly. Your child's incontinent bowel movements may improve while you are in this study but they may not, and there is a chance they may even get worse. This study is designed to learn more about different ways to treat bowel movement accidents. The study results may be used to help others in the future.

Compensation

You will receive compensation for participation in the proposed study. You will be compensated $10 for each week that data are collected and returned to the Marcus Autism Center (total of $100).

Compensation is made using a prepaid debit card. It can be used exactly like a Mastercard. We load money onto your card electronically every time you need to be paid. The card system is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information to verify your identity when you use your card. Emory University is required by law to report any payments we make to the IRS. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. If you have any questions or concerns about the card system or the use of your personal information, please ask. If you are concerned about confidentiality, you can decline payment and still participate in the study.

In Case of Injury

If you get ill or injured from being in the study, Emory and Children's Healthcare will help you get medical treatment. Emory and Children's Healthcare and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory and Children's Healthcare or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Nathan Call at telephone number 404-785-9428. You should also let any health care provider who treats you know that you are in a research study.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Other Treatment Outside this Study

If you decide not to enter this study, there is care available to you outside of this research. You may still be added to the waitlist at the Marcus Autism Center for the assessment and treatment of bowel movement accidents. The study doctor will discuss this with you. You do not have to be in this study to be treated for bowel movement accidents.

Who owns my study information?

If you and your child join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that was already collected may be still be used for this study.

Confidentiality

Emory and Children's Healthcare of Atlanta (CHOA) will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Medical Record

If your child is or has been an Emory or CHOA patient, he/she has an Emory or CHOA medical record. If your child is not and has never been an Emory or CHOA patient, he/she does not have one. An Emory or CHOA medical record will be made for your child if an Emory or CHOA provider or facility gives your child any services or procedures for this study. Copies of the consent form/HIPAA authorization that you sign will not be put in your Emory or CHOA medical record.

Emory or CHOA may create study information about your child that can help with your child's care. For example, the results of study tests or procedures. These study results will be put in your child's Emory or CHOA medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your child's medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

We will take reasonable steps to keep a copy of the consent and HIPAA authorization forms you sign out of Emory or CHOA medical records system. If we aren't successful in keeping these forms out, despite our efforts, we will take steps to remove them. If they cannot be removed, we will take steps to limit access to them. Emory and CHOA do not control results from tests and procedures done at other places, so these results will not be placed in your Emory or CHOA medical record. They will likely not be available to Emory or CHOA to help take care of your child. Emory and CHOA do not have control over any other medical records that your child may have with other healthcare providers. Emory and CHOA will not send any test or procedure results from the study to these providers. If you decide to be in this study, it is up to you to let your health providers know.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI.

PHI that Will be Used/Disclosed: The PHI that we will use or share for the main research study includes:

Medical information about your child including your child's medical history and present/past medications. Results of procedures and tests your child has before and during the study. Assessment data for encopresis Treatment data for encopresis Research study records. We collect several identifiers including name, address, phone number, date of birth,
and dates of study entry and exit. The entire research record for up to seven years after the study is over. Purposes for Which Your PHI Will be Used/Disclosed: We will use and disclose your child's PHI for the conduct and oversight of the research study. We will use and share your child's PHI to provide you with study related treatment. We will also use and share your child's PHI to conduct normal business operations. We may share your child's PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, and Institutional Review Boards (IRBs). If you leave the study, we may use your child's PHI to determine your child's health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law: We will use and disclose you and your child's PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate: By signing this form, you give us permission to use and share your child's PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI: The following people and groups will use and disclose your child's PHI in connection with the research study:

The Principal Investigator and the research staff will use and disclose your child's PHI to conduct the study and give your child study related treatment. Emory and CHOA may use and disclose your child's PHI to get payment for study related treatment and to run normal business operations. The Principal Investigator and research staff will share your child's PHI with other people and groups to help conduct the study or to provide oversight for the study. The Department of Defense is funding the study. They may use and disclose your child's PHI to make sure the research is done correctly and to collect and analyze the results of the research. They may disclose your child's PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study. The following people and groups will use your child's PHI to make sure the research is done correctly and safely: The principal investigator, the project coordinator, the research assistant, and clinical staff employed by CHOA. Emory offices that are part of the Human Research Participant Protection Program and those involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research. Government agencies that regulate the research including: Food and Drug Administration. CHOA offices involved in the study administration and billing. Research monitors and reviewer. Accreditation agencies. Emory Department of Finance and Greenphire will use your PHI for compensation purposes. Expiration of Your Authorization: As this is a research study, your authorization will not expire. You may, however, revoke your authorization later.

Revoking Your Authorization: If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Dr. Nathan A. Call
1920 Briarcliff Road
Atlanta, Georgia 30329

At that point, the researchers would not collect any more of you and your child's PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know: Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical

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information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people for purposes besides this study.

National Database for Autism Research
Data from this study will be submitted to the National Database for Autism Research (NDAR). Your name, address, and phone number will be removed before it is sent to NDAR. This information will be replaced with a code number. Thus, your personal information will remain protected.

Withdrawal from the Study
You have the right to leave a study at any time without penalty. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.
The researchers and sponsor also have the right to stop your participation in this study without your consent if:

They believe it is in your best interest; You were to object to any future changes that may be made in the study plan; Or for any other reason. Contact Information

Contact Nathan Call, principal investigator at 404-785-9428

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care at Children's Healthcare of Atlanta and has a question about your rights, please contact Sarah Marie Huban, Director of Research Administration at 404-785-9323.

Research Study Data Sharing: The study staff of this study will have access to the test results and other research information obtained as part of this study. The study staff of this study will also have access to other tests and procedures done for standard of care, as needed for the conduct of this study.

By initialing in the text box, you agree to share the information obtained as part of this study with the study staff of other studies you may be part of at the Marcus Autism Center. Such studies should also have a statement like this one, and your consent, to be able to obtain or release your information to use in this study.

_____
(If you agree to share data, initial in the text box. If you decline to share data, write "Decline" in the text box.)

Consent and Authorization Please print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent to keep.

Name of Subject

_____
(Please enter the child's first and last name.)

Signature of Legally Authorized Representative

_____

Date and Time

_____

Relationship to Subject

◯ Mother
◯ Father
◯ Legal Guardian
◯ Other

Other relationship to subject

_____

Encopresis copy of consent form

[Attachment: "Consent_DoD_10.16.19_Clean.docx_Exp20220427.pdf"]

Encopresis Revocation Letter (in the event you wish to revoke authorization or withdraw from the study)

Save for your records!

[Attachment: "Encopresis Revocation Letter.pdf"]