The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Telehealth Delivery of Treatment for Sleep Disturbances in Young Children with Autism Spectrum Disorder

Sponsor: Department of Defense
Principal Investigator: Cynthia R. Johnson, PhD, 216 215 7654
Study Coordinator: Leah Barto, 216-448-6392
After hours phone contact: 216 448 6400 and ask that Dr. Johnson be paged

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you will have with the research team. Once you receive this document, please look over and we will discuss with you in detail during a telephone conversation. It is also for use as a reference during the study.

Please note:

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at anytime.**

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

Your child is being asked to take part in this study because s/he has been given a diagnosis of autism spectrum disorder and has problems sleeping. The purpose of this study is to compare the benefits of structured parent training (SPT) to structured parent education program (SPE) for reducing sleep problems in young children with autism spectrum disorder. The information and procedures in both SPT and SPE have been used before, but this project will evaluate whether they can be delivered via telehealth platform with similar effectiveness. That is, instead of meeting in person, we will meet using a secured internet site operated by the Cleveland Clinic. Because the "visits" (ie training or education sessions) will occur electronically, it is necessary for the household to have the following technological specifications: internet connection and smart phone (iPhone or Android) or tablet (iPad or other type of tablet). If needed, the study can provide these (mobile internet access and iPad) for purposes of the study.

What is involved if you decide to take part in this research study?

This is a 10 week randomized trials with a follow-up visit at 16 weeks. The interactions between you, the parent, and the study team, will take place electronically (telehealth) through Cleveland Clinic express care online program. Participants are randomly assigned (flip of coin) to either the SPT or SPE group. The tables on page 3 provide detailed descriptions of what each group will consist of. Before you are given a group assignment to either the SPT or SPE group, each child is evaluated to determine whether the study is appropriate for that child. This assessment will be conducted online via Cleveland Clinic Telehealth platform or telephone and RedCap (secure, online data collection). The initial screening session should take about an hour. The assessment may include any or all of the following: health history, medication history, a review of current treatments, administration of standard tests for diagnosing autism, a review of daily living skills, as well as eating and sleeping habits.

Once eligibility has been established, each parent and child will complete the measures listed under baseline, and will be assigned to either SPT or SPE sessions with a therapist. Baseline measures will be completed again at week 5 and week 10, and a 16 week follow up will assess the effectiveness of your sessions with the therapist. Altogether, including eligibility screening, the study will require approximately12hours of your time.

Both the SPT and SPE programs consist of 5 sessions that will be conducted using Cleveland Clinic secured telehealth and REDCap (for completing questionnaires online). You will be provided instructions in how to use both and we will discuss options for your use (using smart phone, iPAD or computer). Each session takes between 60- 90 minutes. We will also ask you to provide photographs of your child's room or sleep environment but not of your child. We will ask you not to include your child in the photographs or anything else that would clearly identify your child or your family. These photos will help the research staff in developing recommendations and will be destroyed when your child is finished the study. The five sessions provide either instruction in techniques, which are designed to prevent or decrease sleep problems and to promote positive bedtime behaviors or educational information on various topics related to young children with an ASD. During the course of each session, therapists complete a checklist that indicates your involvement and understanding of in-session materials. You may also be asked to complete out of session homework assignments. The therapist will also ask you to complete a parent satisfaction form when you have completed the study. As with all other data collection in the study, this will come to you as an email link,

The following table details the assessment measures that are part of this study and the time it will take to complete them. The measures ask general questions about your child and your family, your child's sleep, your child's daytime behavior, your sleep and your sense of well being and feelings of stress related to your child. We can provide you copies in advance for your review. As a participant of this study you have the right to not answer questions that you find sensitive. The measures for the study will be sent to you via a REDCap link (electronic and secure) with instructions in either a text or email; whatever means you chose. A study member will contact you by telephone to review before you complete them.

Table 1. Schedule of Measures and Completion times (in minutes)	**Screen**	**Baseline**	**Wk 5**	**Wk 10**	**Wk 16**
Parent Completed Measures					
Demographics, Medical & Developmental History	30				
Modified Checklist for Autism in Toddlers (M-CHAT) or Social Communication Questionnaire (SCQ)	10-15				
Composite Sleep Index (CSI)	5	5	5	5	**5**
Children's Chronotype Questionnaire (CCTQ)		10-20	10-20	10-20	
Aberrant Behavior Checklist (ABC)		15-20	15-20	15-20	
Parent Stress Index (PSI)		10-20	10-20	10-20	
Parenting Sense of Competence Scale (PSOC)		15	15	15	
Parent Health Questionnaire (PHQ)		5	5	5	
Pittsburgh Sleep Quality Index (PSQI)		**10**	**10**	**10**	

As stated above, you will be "randomized" (like a flip of a coin) to either SPT (Table 2 below) or SPE (Table 3 below).

The next table provides an outline of the session of Sleep – Parent Training (SPT)

Table 2. SPT Session Outline	
Sessions	**Topics Addressed**
A. Importance of Sleep & Basic Behavioral Principles	• Introduce overall goals. • Introduce importance of sleep and the need to improve quality of sleep in children with ASD. • Introduce antecedent, behavior, and consequence model. • Introduce the concept of the functions of behavior. • Introduce general sleep hygiene guidelines. • View bedroom / sleeping environment
B. Addressing Prevention Techniques & Bedtime Routines	• Discuss preventive techniques .specific to children with ASD. • Develop daily schedule as well as bedtime schedule / routine. • Develop visual schedule that supports daily/bedtime routine. • Review how to develop social stories, when appropriate.
VSEE Evening Session	Parent coaching at bedtime
C. Addressing the Use of Extinction & Procedures for Bedtime Struggles, Night Wakings and Early Morning Wakings	• Introduce concept of extinction / planned ignoring to decrease behaviors. • Introduce use of different extinction techniques to specifically address sleep problems (bedtime struggles, night wakings, early morning wakings). • Introduce concept of reinforcers and teach contingent implementation of reinforcement. • Decide upon reinforcement, extinction, & scheduled awakening procedures.
VSEE Evening Session	Parent coaching at bedtime
D. Addressing Delayed Sleep Onset & Sleep Association Procedures	• Introduce the concept of stimulus control and its relationship to sleep behaviors. • Introduce faded bedtime routines as well as review bedtime routine. • Introduce teaching new sleep associations. • Develop specific procedures for teaching new sleep associations.
VSEE Evening Session	Parent coaching at bedtime
E. Booster & Maintenance Session	• Revise & "tweak" procedures / techniques based on review of sleep diary data and parent report of progress. • Discuss strategies for maintenance of behavior change. • Generate ideas of what to do if changes do not / have not maintained.
OPTIONAL MATERIALS *Address Noncompliance* *Address Nighttime Fears*	• Introduce concept of compliance / noncompliance • Review steps for compliance training • Review procedures for increasing compliance around bedtime and nighttime • Review why children may have fears at nighttime • Discuss with parent's their child's fears • Develop plan to reassure child, teach the child "brave skills" • Teach parents to implement systematic exposure for severe/specific fears

Table 3 includes the topics of the sessions of SPE

Table 3. Sleep Hygiene and Parent Education (SPE) Outline	
Sessions	**Goals & Topics Addressed**
A. ASD Diagnosis	• Discuss diagnosis & family's adjustment • Prevalence of ASD in the population and etiology • Review service delivery models • Review sleep diary to be completed for next session
B. Sleep Hygiene	• Introduce types of sleep disturbances observed in ASD • Review CSI and Sleep Diary with parent(s) • Develop plan to address identified bedtime / sleep problems • Develop data collection to monitor progress
C. Understanding & Interpreting Clinical Evaluations	• What do IQ tests measure & understanding the scores • Speech, language and communication measures • Fine motor measures • Review selected behavioral ratings
D. Advocacy and Support Services	• Provide information about national & local support services • Parent to parent contact • Advocacy services and how to use them
E. Treatments & Treatment Planning	• Information on evidence-based / best practices • Information on other alternative treatments & use of supplements • Review of current services for child • Discuss progress and current concerns • Discuss other treatment options available for children with ASD

ALTERNATIVES

This study is being performed for research purposes only. The alternative to the study is not to participate in the investigation and seek alternative therapies or treatments. A listing of therapy options was provided to you in the report you received when your child received the diagnosis of autism spectrum disorder.

If you decide not to take part in this research study, your child will continue to receive care as he/she routinely would at the Cleveland Clinic

3. RISKS

What are the risks of participating in the research study?

Potential risks of participating in this study include the following: First, participation requires a substantial commitment of time. This time commitment is not only the time involved in the delivery of the sessions, but also the time involved in assessments, keeping the sleep diary, etc. These data will be collected for research purposes and may offer no direct benefit to you or your family. Thus, the time and effort spent may not produce the intended results. Second, although we think it is unlikely, it is possible that the intervention could produce adverse effects on your child's behavior (e.g., increased bedtime or night time problems due to an extinction burst). Third, although the questionnaires and interviews used in the study are commonly used in research and clinical settings, you may have some discomfort in responding to questions asked during the study interviews or questionnaires. If you are not comfortable answering a question at any time, you are free to skip it.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a risk of loss of confidentiality. Your information will be stored in a locked cabinet that is accessible only to a member of the study team. Audio-recordings will be taken of all sessions and are for the purpose of documenting treatment accuracy, 10% will be rated on acccuracy. The recording will be stored on a Cleveland Clinic secured drive on a password protected computer and only be accessible by appropriate research personnel. The information obtained from all aspects of the study will be de-identified for analysis. If the sponsor were to publish information from this trial, the results would only be mentioned in aggregate/total form. You would not be individually identified.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project. This does not exclude you from participating in this study.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed on the first page of the consent.

Confidentiality Risk:

There is a small risk that your child's personal health information or your child's participation in this study may be disclosed. The Cleveland Clinic upholds the "Minimum Necessary" standard, as recommended by the federal government through HIPAA (the Health Insurance Portability and Accountability Act). Information that may identify your child is removed from his or her assessment data. Only a small number of necessary study personnel are permitted to access your child's information, which will be stored in a locked cabinet on a secure floor in a limited access building on the Cleveland Clinic campus. In addition, any data stored in a computer is password protected. Your child's participation and the results of the research may be placed in your child's medical records. No information will ever be released or published in a way that will identify a specific individual. Although every effort will be made to protect the confidentiality of your child's records, this cannot be guaranteed.

Your child's identity will be kept anonymous by using two identification numbers. The first is the Sleep Study ID which is assigned by the Cleveland Clinic research staff. The second is a global unique identifier (GUID). Using the GUID, de-identified data will be exported to the National Database for Autism Research (NDAR) as required by the funding agency. NDAR is an NIH-funded data repository that aims to accelerate progress in autism spectrum disorder (ASD) research through de-identified data sharing and the reporting of research results. NDAR is one of several databases that make up the National Institute of Mental Health Data Archive (NDA).

4. BENEFITS

What are possible benefits of participating in the research?

The possible benefits of participation in this study are the improvement of your child's sleeping and bedtime behaviors; however there is no guarantee that your child will receive such benefits. SPT is a specific set of techniques designed to reduce sleep problems and may be beneficial. SPE will provide potentially useful information about ASD. Information alone may be beneficial.

5. COSTS

Are there any costs to you if you participate in this study?

There are no cost to you and your child's participation. The Sponsor will pay for or provide all services required as part of your participation in this study. The telehealth sessions will not be charged to you or your insurance company. If you have limited internet plan or no access, we can provide the needed mobile internet connection (Verizon Mobile Hotspot) for purposes of the study. There will be no cost to you.

6. COMPENSATION

All families taking part in the study will be paid a payment of $25 for the initial screening and baseline, $25 for each of the subsequent assessment appointments (weeks 5, 10 and 16), and $25 for each session. This is a total of $250 for completing the study.

This reimbursement may be considered taxable and will be reported to the Internal Revenue Service when total payments to a research participant exceed $600 annually. This may apply to you if your child is participating in more than one research study. For tax purposes, the Cleveland Clinic is required to notify the IRS and provide an IRS 1099 to each individual exceeding the $600 limit. Given your child's age, your name, address and social security number are needed to process these payments and the check will be made out to you

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

If physical injury occurs due to your child's involvement in this research, medical treatment is available, but your medical insurance must pay the cost of treatment. Such medical treatments that are not covered by your medical insurance shall not be paid by the Cleveland Clinic. Compensation for lost wages and /or direct or indirect losses is not available. The Cleveland Clinic will not voluntarily provide compensation for medical expenses or any other compensation for research-related injuries. Further information about research-related injuries is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

HIPAA Authorization (Privacy and Confidentiality)

Cleveland Clinic has rules and procedures to protect information about your child. Federal and State laws also protect your privacy.

The research team working on the study will collect information about your child. This includes his or her health information, data collected for this research study and personal identifying information including your child's name, address, date of birth and other identifying information.

Generally, only people on the research team will know your child's identity and that he or she is in the research study. However, sometimes other people at Cleveland Clinic may see or give out your child's information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may need to see your child's information for this study. Examples include safety monitors and the sponsor of the research (Department of Defense), and their agents. Cleveland Clinic will do our best to ensure your child's information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your child's information may not be covered by this promise.

You do not have to give this permission to use and give out your child's information; however your child will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your child's information has no expiration date.

You may cancel your child's permission to use and disclose your information at any time by notifying the Principal Investigator in writing***, Cynthia R. Johnson, PhD, 2801 Martin Luther King Jr Drive CRS 10, Cleveland, Ohio 44104.*** If you do cancel your permission to use and disclose your child's information, your child's participation in this study will end and no further information about your child will be collected. Your cancellation would not affect information already collected in the study.

Clinical Trials Website

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U. S. law. This Website will not include information that can identify your child. At most, the Website will include a summary of the results. You can search the Website at any time.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions about the research or develop a research-related problem, you should contact Cynthia R. Johnson, Ph.D. (216)215 7654or 24-hour on-call number (216) 448 6400 and ask that Dr. Johnson be paged. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your child's health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your child's study doctor your decision to ensure a safe withdrawal.

If you choose to withdraw from the study you will be asked to complete one final assessment session.

11. SIGNATURES

Permission of Parent/Legal Guardian

I have read and I and my child have had verbally explained to us the above information and have had all my questions answered to my satisfaction. I understand that my child's participation is voluntary and that I may stop my child's participation in the study at any time. Signing this form does not waive any of my child's legal rights. I understand that a copy of this consent will be provided to me. By signing below, I give permission for my child to take part in this research study.

_____
Printed Name of Parent/Guardian

_____ _____
Parent/Guardian Signature Date

_____
Printed Name of Child

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date