INFORMED CONSENT FORM

Official title: The use of a program like The Listening Program® with bone conduction headphones changes hypersensitivity to sound and behavioral responses associated with flight/fight responses of children with Autism Spectrum Disorder (ASD) therefore increasing adaptive life skills.

NCT number: NCT05009095

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Title of Study: The use of a program like The Listening Program ® with bone conduction headphones changes hypersensitivity to sound and behavioral responses associated with flight/fight responses of children with Autism Spectrum Disorder (ASD) therefore increasing adaptive life skills.

Consent to be part of a Research Study
To be conducted at
Children's Medical Center of Dallas and any of its affiliated entities

Key Information about this Study

The prevalence of Autism Spectrum Disorder (ASD) is increasing and many children with ASD experience hypersensitivity to sensory input, in particular sound. Children with ASD who are hypersensitive to sound can have negative reactions to a variety of sounds in environment, which can lead to difficulty doing everyday tasks. There is limited research on what treatments might be effective to treat hypersensitivity to sound for children with ASD. The purpose of this study is to learn if one treatment - the Listening Program's ® Spectrum Music with Wave (bone conduction) headphones – can reduce hypersensitivity to sound and improve behavior and function for children with ASD.

If you choose to participate in this study, , your child will participate in the Listening Program® at home for 40 weeks (about 10 months), with a 3 month follow up after completion of Listening Program®. Participants will be asked to meet three times. During the first visit, you will be given The Listening Program® along with education on how to use the program. You will also complete study forms and questionnaires. During the second visit, you will return The Listening Program® equipment and complete study forms and questionnaires. You will be given the option to meet either in person or with a hospital approved virtual platform for the third visit to complete study forms and questionnaires. You will also check-in with the researchers 3 times (every 10 weeks), between the first and second visits, over the phone or with a hospital approved virtual platform.

Benefits to participating in this study include the opportunity for your child to participate in the Listening Program® at no cost to you, as well as education about hypersensitivity to sound from an experienced occupational or physical therapist. This study poses no more than minimal risk to participants and their families. Some of the possible risks include discomfort due to headphones slipping out of place or if volume is raised to an uncomfortable level. To help reduce the possibility of discomfort during treatment, you will receive instructions on safe and appropriate usage of the Listening Program® at home including parental supervision while listening. In addition, any time information is collected there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Information about this form

Enrolling Children or Incompetent Adults

If you are providing consent for someone else, for example your child, your next-of-kin or someone for whom you are the legal guardian or are designated as a surrogate decision maker on a medical power of attorney, please note that in the sections that follow, the word "you" refers to the person you are providing consent for.

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

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Your physical or occupational therapist maybe a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another physical or occupational therapist who is not part of this research study. You do not have to take part in any research study offered by your physical or occupational therapist.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff, Children's Health staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Suzanne Vercontaire, OTR/L, the Co-Investigators are Caitlin Deville, PT, MPT, DSc and Kassie Missell, OTR/L, OTD at the Department of Rehabilitation and Therapy Services at Children's Health.

Conflict of Interest: None

Funding: This study is funded by Children's Health.

Purpose – "Why is this study being done?"

This study is being done to find out if the use of the Listening Program ® can reduce hypersensitivity to sound and improve behavior and function in children with autism spectrum disorder (ASD). More and more children are being diagnosed with ASD. According to the Center for Disease Control (CDC), in the year 2000, 1 in 150 children had ASD. In 2016, approximately 1 in 54 children has been identified with (ASD). ASD is 4.3 times more common in boys Children with ASD often have difficulty processing sensory information, including hypersensitivity to sound. Children with ASD who are hypersensitive to sound can have negative reactions to a variety of sounds in their environment and this can keep them from fully participating in everyday life skills. For example, children may hold their ears to protect them from the sound of a toilet flushing and avoid using the toilet.

You are asked to participate in this research study of hypersensitivity to sound for children with ASD. There is a growing need for evidenced-based treatments for children with ASD and hypersensitivity to sound. To relieve discomfort and lessen behavioral reactions to a variety of environmental sounds and support improved participation in everyday life skills. The researchers hope to learn if one treatment - the Listening Program's ® Spectrum Music with Wave (bone conduction) headphones - is effective for treating hypersensitivity to sound for children with ASD.

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

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Information about Study Participants – "Who is participating in this research?"

You and your child are being asked to take part in this study because your child has a diagnosis of autism and is hypersensitive to sound.

How many people are expected to take part in this study?
This study will enroll approximately 5 to 8 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will meet in person at a Children's Health Specialty Center with the researchers and study staff for an initial visit. This visit will take 1 – 2 hours and you will be given The Listening Program® equipment along with education on how to use the program. You will also complete study forms and questionnaires. You will begin using the program at home, and you will meet on the phone or with a hospital approved virtual platform for 5 – 15 minutes check-in meetings every 10 weeks. After 40 weeks of using The Listening Program, you will meet in person again at a Children's Health Specialty Center for 1 – 1.5 hours to return the equipment and complete questionnaires. You will have a final visit 3 months later, and you will be given the option to meet either in person or with a hospital approved virtual platform to complete questionnaires. At each visit or check-in, you will be given the opportunity to ask questions.

Study Procedures - as a participant, you will undergo the following assessments:

If you agree to be in this study**,** you will be asked to meet 2-3 times at a Children's Health Specialty Center. Or, if you prefer, your 3rd visit can be completed with a hospital approved virtual platform. Additionally, you will be asked to meet on the phone or with a hospital approved virtual platform 3 times, between the 1st and 2nd in-person visits.

Visit 1. (In-person, 90 minutes to 2 hours)
During this meeting:
We will go over the following topics:

- Consent to participate in research
- Auditory Sensory Over Responsivity (SOR) (Hypersensitivity to sound)
- The use of the listening program and "Wave" bone conduction headphones.

You will complete 4 questionnaire-based assessments

- The Pediatric Evaluation of Disability Inventory (Autism)
- Adaptive Behavior Assessment System-3
- Sensory Processing Measure (Home Edition)
- Autism Treatment Evaluation Checklist (ATEC)

You will fill out the demographic information sheet

We will answer any questions you have about the research study

We will checkout loaner equipment for you take home and use for 40 weeks including: iPod Touch with The Listening Program Spectrum music, amplifier, and Wave (bone conduction) headphones

Phone or hospital approved virtual platform meeting 1 (5 to 10 minutes)
At 10 – 11 weeks of treatment, you will have a phone meeting with one of the investigators to check in and answer any questions you may have.

Phone or hospital approved virtual platform meeting 2. (10 to 15 minutes)
At 20 – 21 weeks of treatment, you will have a phone meeting with one of the investigators to check in, answer any questions you may have, and complete the Hearing subsection on the Sensory Processing Measure-Home form.

Phone or hospital approved virtual platform meeting 3. (5 to 10 minutes)
At 30 - 31 weeks of treatment, you will have a phone meeting with one of the investigators to check in and answer any questions you may have.

Visit 2. (In-person, 60 to 90 minutes)
At the 41st week, during this meeting:
You will answer 4 questionnaire-based assessments

- The Pediatric Evaluation of Disability Inventory (Autism)
- Adaptive Behavior Assessment System-3
- Sensory Processing Measure (Home Edition)
- Autism Treatment Evaluation Checklist (ATEC)

We will answer any questions you have about the research study

You will return all loaner equipment in good working condition, including: iPod Touch with The Listening Program Spectrum music, amplifier, and Wave (bone conduction) headphones

Visit 3. (In-person or via hospital approved virtual platform, 60 to 90 minutes)
After 3 months after completion of the listening program, you will answer 3 questionnaire-based assessments

- The Pediatric Evaluation of Disability Inventory (Autism)
- Adaptive Behavior Assessment System-3
- Sensory Processing Measure (Home Edition)
- Autism Treatment Evaluation Checklist (ATEC)

We will answer any questions you have about the research study

The results from The Pediatric Evaluation of Disability Inventory (Autism), Adaptive Behavioral Assessment System-3 the Sensory Processing Measure (Home Edition), and Autism Treatment Evaluation Checklist (ATEC)in this study are designed for research not for medical or therapeutic purposes.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician.

Risks – "What are the risks of participation in the research?"

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Risks from the research

There is no standard of care for treatment for hypersensitivity to sound for children with ASD. Many children with ASD receive treatments such as occupational therapy – including general treatment for sensory processing disorder, speech therapy, and applied behavior analysis (ABA) treatment. However, none of these treatments specifically address the underlying impairments related to hypersensitivity to sound. The investigators have designed this study to learn how well this treatment for hypersensitivity to sound for children with ASD (The Listening Program) compares to no treatment for hypersensitivity to sound.

Risks from the specific research procedures (drug(s), interventions, or procedures)

This study poses no more than minimal risk to participants and their families. The questionnaire-based assessments used in the three data collection sessions are often administered by occupational therapists in pediatric rehabilitation settings, among other places, and are not known to cause any harm. Any adverse physical or psychological harm to study participants during the administration of Listening Program ® Spectrum music with Waves ™ (bone conduction) headphones is unlikely. The parent will have instructions on safe and appropriate usage of the Listening Program ® at home, including recommendation to supervise their child during usage, how to put on the headphones correctly (correct ear placement will be noted on the headphones), and how to accommodate fit of headphones for small children (eg, using a headband or rolled up bandana to keep them in place). However, if the child is unattended while doing the Listening Program, possible risks include: chewing or otherwise tampering with the cord, moving the plug from the correct placement in the amplifier, raising the volume to an uncomfortable level, or discomfort due to headphones slipping out of place or placed backwards on the child's head. There may also be the risk of strangulation from the cord if the child is left unsupervised.

For more information and/or questions about risks ask one of the researchers or study staff.

Are there Risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The loaner equipment will need to be returned in good working order if you decide to withdraw early. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes completion of 3 study assessments. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time will likely not increase your risk. However, it may affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.
If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

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If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating in this study include your child will be provided with listening-based therapy at no cost. The findings from this study will begin to fill in a gap of knowledge regarding the utilization of listening-based programs for the treatment of hypersensitivity to sound in children with autism. This study will also serve as a basis for other studies investigating the potential benefits of listening based programs.
The parents, legal guardians, and children who participate in the study will be provided with an oral report using lay terminology that summarizes changes in the questionnaires following the study, which they may consider a potential benefit to participation in the study. Aside from this there is no other direct benefit to participants.

There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

There are other options available to you. Your other choices may include:

1) Getting treatment or care without being in a study which may include:
   a) listening based programs (The Listening Program, or others)
   b) Other types of auditory stimulation
   c) Environmental modifications to avoid noxious stimulus (noise blocking headphones, etc.)
2) Taking part in another study
3) Getting no treatment

Payments – Will there be any payments for participation?

You will be given a $20 Clincard at the end of the 2nd visit, after returning loaner equipment in good working order, to help cover the cost of transportation to study related in-person visits.

You will be issued a Children's ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of study related in-person visits. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Costs – Will taking part in this study cost anything?

There are no costs to participating in this study, beyond the cost of transporting your child to the in-person visits.

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Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

How will my information be used?

Your personal information collected during this study will not be used or distributed for future research studies even if the information is de-identified and cannot be linked back to you.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?

Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- Information that is created or collected during your participation in the study including your child's medical and treatment history
- Information you give us during your participation in the study such as during interviews or from questionnaires
- Demographic information you give us like your age, your child's grade in school, and your address

We will get this information by asking you – we will not be reviewing you or your child's medical charts or talking to your doctors.

How will your PHI be shared?

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center, Children's Medical Center of Dallas and any of its affiliated entities.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.
- Your de-identified data and assessment of findings may be shared with Advanced Brain Technologies, the company that makes and sells The Listing Program.

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If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
To protect your privacy, the study staff will use code names and numbers instead of your name, to identify your health information. Code names and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of Children's Health Specialty Center Richardson for review or analysis. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.
After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to the study investigators. The Principal Investigator for this study is Suzanne Vercontaire, OTR/L and the Co-Investigators are Caitlin Deville, PT, MPT, DSc and Kassie Missell, OTR/L, OTD at the Department of Rehabilitation and Therapy Services at Children's Health. The mailing address is 3661 North Plano Road Suite 3500, Richardson, Texas, 75083. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. Requests to review PHI before the end of the study will be reviewed on a case by case basis.

After the study is completed, you have the right to see and copy the assessment results we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends, and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:
Suzanne Vercontaire, OTR, Principal Investigator

Primary contact:

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Suzanne Vercontaire, OTR can be reached at 469-488-7331 or 469-488-7300 during normal business hours.

If primary is not available, contact
Co-Investigator: Caitlin Deville, PT, MPT, DSc or Co-Investigator: Kassie Missell, OTR/L, OTD
can be reached at 469-488-7331 or 469-488-7300 during normal business hours.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

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Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Surrogate Signature Section

			AM PM
Printed Name of Participant	Signature of Participant Giving Assent (*If incapable of signing, person obtaining consent should initial here*)	Date	Time
			AM PM
Printed Name of Person Giving Consent for Participant (If applicable)	Signature of Person Giving Consent ☐Parent/☐Guardian/☐Legally Authorized Representative	Date	Time
			AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

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Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:
By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM