CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: Feasibility of a Home-Based Vestibular Balance Therapy Intervention for Children with Vestibular Hypofunction

UAB IRB Protocol #: IRB-300010569

Principal Investigator: Jennifer Christy, PT PhD

Sponsor: Foundation for Physical Therapy Research

For Children (persons under 18 years of age) participating in this study, the term "You" addresses both the participant ("you") and the parent or legally authorized representative ("your child").

General Information	You and your child are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to find out the best ways to provide physical therapy exercises for children with inner ear problems.
Duration & Visits	You and your child will be in this study for 8 weeks. Your child's balance and vision will be tested 3 times. We will teach you and your child to do the exercises at least 5 days per week at home. The physical therapist will work with you one time per week to progress the exercises. The total time will take approximately 29 hours over 8 weeks.
Overview of Procedures	• You and your child will visit the Vestibular Ocular Research Clinic twice. Visit #1 will last 2 hours and we will test your child to determine inner ear function. Visit #2 will last 2 hours where we will do physical therapy tests of your child's balance and ability to see with the head moving. • You will help your child do the exercises 5 times per week, 20 minutes per day, at home. The physical therapist will work with you and your child 1 time per week either in the clinic, or at your home. It is your choice on where you would like to work with the therapist. • After 4 weeks, and then again after 8 weeks, you will return to the Vestibular Ocular Research Clinic (1 hour each visit), and we will do the physical therapy tests again of your child's balance and vision.
Risks	The most common risks include fatigue from doing the exercises, redness on the face from the goggles during testing, and redness on the skin from the electrodes during the audiology tests. Your child might also become dizzy when doing some of the tests that involve head movement or lose their balance during the balance tests.
Benefits	Your child may or may not benefit from participation in the study. The exercises are designed to improve balance and vision during head movement.
Alternatives	You may choose not to participate in the study and may drop out at any time.

Purpose of the Research Study

We are asking you and your child to take part in a research study. The purpose of this research study is to understand how the vestibular system, the part of the inner ear that is responsible for balance and sensing movement, is affected in children with sensorineural hearing loss and how we may be able to improve its function through fun, at-home exercises. We will recruit a total of 15 children, ages 6-12 years, to complete this study.

Study Participation and Procedures

1. If you agree to the study, the first two testing sessions will happen at the Vestibular Ocular Research Clinic located at UAB Eye Care in the UAB School of Optometry, Henry Peters Building, 1716 University Blvd, room G070T. Each visit will take approximately 2 hours. The first visit will be to test your child's inner ear function. The 2nd visit will be to do physical therapy tests of your child's balance and ability to see with the head moving. We will also teach the exercises to you and your child and give you the equipment that you will need at home.

> If your child scores below normal values on these tests, you and your child will be invited to participate in the exercise intervention part of the study. The first 3 children who score at or above normal values on these tests will be invited to participate in the placebo intervention, to be completed by the control group in future studies. A placebo intervention includes activities that take the same amount of time and therapist attention as the exercise intervention but are not expected to improve testing scores.

3. If your child is eligible to participate in the exercise intervention, you and your child will be taught how to complete the exercises at home for 8 weeks, 20 minutes per day, 5 days per week. Once a week, you will meet with the Principal Investigator and physical therapist, Dr. Jennifer Christy, either at your home or at the Vestibular Ocular Research Clinic to review and progress the exercises. Your child will read children's books or identify pictures as you turn your child's head; balance while standing still; and balance while walking and moving. You can let Dr. Christy know where you would like to meet for these sessions.

4. At 4- and 8-weeks after initiation of the intervention, you and your child will return to the Vestibular Ocular Research Clinic for a repeat examination that will take about 2 hours.

The tests and procedures that make up this protocol are explained below.

Visit #1: UAB Vestibular Ocular Research Clinic:

Your child will undergo vestibular (inner ear) function testing to be completed by the primary investigator, Dr. Jennifer Christy:

oVEMP AND cVEMP Testing

The Vestibular Evoked Myogenic Potential (VEMP) is a test of how well the inner ear works in response to vibration stimulation. There are two parts of the inner ear we will test; the saccule (cVEMP) and utricle (oVEMP).

cVEMP

We will clean the skin over your child's neck and forehead, and place recording electrodes (like stickers) on the neck muscles, on the forehead and on the upper chest. We will then place a device on your child's forehead that will deliver gentle taps. Your child will be asked to keep their head turned and lifted slightly as the taps are delivered This will take about 30 seconds. The test will then be repeated on the other side.

oVEMP
Following the cVEMP, we will remove the electrodes from the neck and place new electrodes under the eyes. Your child may experience brief discomfort when we remove the electrodes (like pulling a band-aid off), but it will go away. We will again place a device on your child's forehead that will deliver gentle taps. Your child will be asked to keep looking up as the taps are delivered to the forehead. This will take about 30 seconds. After this, we will remove the electrodes and, again, there might be some redness or discomfort where they were placed but it will pass.

Video Head Impulse Test
For this test, your child will be sitting in a chair and focusing on a sticker on the wall in front of them. Your child will wear goggles that have small cameras recording your eyes. Your child will be asked to keep the eyes open, and the examiner will quickly turn the head quickly in several directions. If the examiner does not turn the head fast enough, or if your child closes their eyes, the trial will need to be repeated. This test will continue until they have completed 10 valid trials for each direction of movement. For this task, the eyes must be opened wide. If your child is having trouble keeping the eyes open as the head moves, we will ask you and your child if we can place tape on the skin on the upper eyelid to hold the eye open. This is a common technique used in eye clinics but may be uncomfortable for some people. Your child will still be able to blink normally but will feel pressure on the eyelid.

Rotary Chair
The rotary chair test allows us to test how well your child can follow a visual target and how the eyes move in response to head movement. Your child will sit in the motorized chair, and we will place seatbelts around your child's lap and shoulders and put padded straps around their ankles. Your child will be asked to remove glasses, if wearing them, and put on goggles like a scuba mask that will measure eye movements. Contact lenses can be left in place. Your child will then be secured with pads on their forehead so that the head will not move much during the test. The examiner will place a headphone with a microphone on your child. The rotary chair is in a small room that will be completely dark when the door is closed. However, cameras will enable us to always see your child, and your child will be able to hear the examiner through the headphones and talk to the examiner through the microphone. At any time, your child can tell the examiner to stop the test and we will immediately do so. If the chair is rotating, it will gently slow down to a complete stop. The first half of tests will test your child's ability to follow a red dot as it moves left/right and up/down. Sometimes the dot will move smoothly from location to location; other times it will jump. Your child's job is to follow the dot with the eyes as well as they can and listen to the tester's instructions.

Following these tests, your child will be asked to be still and look forward as they slowly spin in a circle to the left or the right. In some cases, we will ask your child to focus on a red dot while the chair moves. We will measure eye movements during these tests. Your child will be free to blink at any time, but we need them to keep their eyes open even when in total

darkness so that eye movements can be recorded. We will explain each aspect of the test. Your child can take a break at any time during the testing by letting the examiner know.

Vestibular Oculomotor Research Clinic (Initial Session & Repeat Sessions)
You and your child will go to the Vestibular Oculomotor Research Clinic in the Henry Peters Building at UAB for the subsequent testing sessions. A physical therapist will complete the following vestibular tests on your child.

Sensory Organization Test (SOT)
The SOT tests the ability to maintain balance under various conditions. Your child will be placed in a safety harness and will stand on a force platform, like a specialized weight scale. Safety straps will attach to the harness to prevent falling. The examiner will constantly guard your child throughout the testing to ensure they do not fall. Your child will be asked to stand as still as possible under 6 conditions: 1) Eyes open; 2) Eyes closed; 3) Eyes open, as the visual surround (walls) move in response to your sway; 4) Eyes open as the platform moves in response to your sway; 5) Eyes closed, swaying platform; 6) Eyes open, swaying visual surround and platform. Each condition is measured for 20 seconds, and 3 trials of each condition will be completed. This test will take approximately 10 minutes.

Dynamic Visual Acuity Test
For this test your child will be seated in front of a computer. A soft headband with a motion detector attached to it will be placed around the head. Your child will first be asked to stare at a circle on the screen where the letter E will appear. Your child will tell the examiner which direction the E is facing when they see it (Up, like a W, Right, like an E, Down, like an M, or Left, like a 3). Your child will also have a picture with the E symbols so they can point to them if needed. After this, the examiner will turn your child's head side to side. When the examiner moves the head at the right speed, another E will appear. Your child will need to identify again which direction the E is facing. This test will help us understand how well your child can see while the head is in motion.

Functional Gait Assessment (FGA)
We will ask your child to walk across a 20ft long, 1ft wide path several times. We will ask your child to walk within the 1ft wide path under 10 conditions, for example, at a normal walking speed, as fast as possible, and while moving the head. We will demonstrate each condition, so your child understands what to do. We will walk with your child as they complete this task to catch them if they lose their balance. This test will take about five minutes and will help us understand how well your child can balance while moving and completing different tasks.

Canadian Occupational Performance Measure (COPM):
For this test, we will interview you and your child to determine activities related to balance or vision of importance to you. You will identify the 5 most important activities that you would like to address, the rate each activity on how well your child performs them, and how satisfied you are with this ability. This will give us goals to try to achieve during the intervention.

Repeat Testing
As stated above, if you and your child participate in the intervention or placebo portion of the study you will return to complete this section of the protocol again 4- and 8-weeks after starting the intervention.

Intervention Component
Depending on the result of the Vestibular Ocular Research Clinic vestibular tests, we will classify your child as having either *normal or abnormal vestibular function*. Our goal for this study is to study the exercise intervention on children with *abnormal vestibular function*.

Therefore, we will recruit children until we have enrolled 12 children with abnormal vestibular function into the intervention. We also would like to see how well a placebo intervention is tolerated by children and families and plan to enroll 3 children *with normal vestibular function* in that intervention. Therefore, it is possible that your child may be *ineligible* for an intervention if we have already enrolled 12 children with abnormal function in the first intervention or 3 children with normal function in the second intervention.

We will provide all necessary equipment for you and your child to complete either intervention and will meet once every week with you and your child to monitor your progress with the exercises.

Intervention for 12 Children with Abnormal Vestibular Function

Identifying words or pictures while your head is moving (5 minutes per day)
We will give you access to PowerPoint presentations of reading level appropriate children's books with stories and/or pictures. Your child will read the story or identify small pictures as you move their head right/left (like saying "no") and up/down (like saying "yes"). We will show you how quickly to move their head and show you how to use a metronome to make sure you are moving at the right speed. At the first session, we will determine the proper speed to enable success with identifying the words or pictures. During each weekly check-in, we will adjust the exercises to make them more challenging (e.g., increase the speed of their head movement or the length of the exercise). If you do not have a laptop or tablet to view the presentations, we will provide you with one to use during the study period.

Gaze Shifting (5 minutes per day)
We will provide flashcards with words or pictures for you to place on the walls in a hallway in your house using painter's tape. Your child will walk as quickly as they can while turning their head to read the words or identify the pictures. We will determine a starting intensity (distance between the cards and size of words/pictures on the cards) with you at your visit and attempt to increase the intensity each week.

Static Balance (5 minutes per day)
Your child will stand as still as they can both on the floor and on a foam pad under different conditions: eyes open, eyes closed, eyes covered, with head movements, standing with a narrow base of support, standing on one foot. We will determine the initial difficulty level of the task at your visit and then discuss each week how we may make it more challenging as they improve.

Dynamic Balance (5 minutes per day)
Your child will practice balancing while moving by progressively adding more complex motions such as walking heel-to-toe, walking backwards, walking with eyes closed, and

stepping over objects. Each week we will change the focus and difficulty of this task after discussing your child's progress.

Intervention for 3 Children with Normal Vestibular Function
This intervention will require you to ensure your child completes 10 minutes of reading their material of choice and 10 minutes of active play 5 days per week for 8 weeks. The therapist will meet with you once a week either by zoom or in person.

Intervention Journaling
Regardless of the intervention you and your child complete, we ask that you keep a record of how often you perform each task and you and your child's enjoyment of the tasks. This will help us adjust the tasks, if needed, to make them more fun, easier to complete, and more convenient.

Risks and Discomforts

The tests we will be doing are routinely completed for children who usually tolerate the tests very well. During the tests at Children's of Alabama, your child might become dizzy during the rotary chair tests or the video head impulse test. We will constantly talk to your child during the tests and can stop them at any time. Your child might also have redness on the face and neck following removal of the goggles and neck electrodes. This will go away after a few minutes, like removing swim goggles or a band-aid from the skin.

Your child may lose balance or fall during the balance testing; however, we prepare for that by stopping a trial immediately if they lose balance and by standing near them the entire time. The balance and gait tests we are using are commonly used by clinicians and are not dangerous. Your child might also become dizzy during the dynamic visual acuity test. We will constantly communicate and stop testing if your child becomes uncomfortable. We will provide ample breaks and you may remove your child from the study at any time.

The intervention is to be done 5 days/week. Although we will do our best to make it fun, you might find some of the exercises challenging and get tired. The purpose of the study is to determine if you can do the exercises, so it is OK to rest or stop if you want to. The investigator will check with you each week, and you can call her at any time to ask questions.

As with most research studies, there is a slight risk of the loss of confidentiality. Our team is trained to make every effort to maintain your child's confidentiality.

Benefits

Your child may not benefit directly from taking part in this study. However, this study may help us better understand the best way to treat vestibular problems in children.

Alternatives

The alternative is for you to not participate in the study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it.

The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?

All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

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

Who may use and give out this information?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?

All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- The University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, Children’s of Alabama; the UAB IRB and its staff
- The billing offices of UAB and/or Children’s of Alabama and its billing agents

Why will this information be used and/or given to others?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. Contact Dr. Christy if you want to withdraw from the study.

You may be removed from the study without your consent if the sponsor ends the study, if Dr. Christy decides it is not in the best interest of your health, or if you are not following the study rules.

Cost of Participation

There is no cost for you to take part in this study. All tests, interventions and intervention equipment are provided to you free of charge. You will not be charged for parking when you visit Children's of Alabama or UAB campus.

Payment for Participation in Research
If you are chosen to participate in either of the intervention groups, you will be paid $33.00 for the first two testing visits to the Vestibular Ocular Research Clinic, and $34.00 for the final visit ($100 total). If you withdraw from the study, you will be paid $33.00 for each study visit made to the Vestibular Ocular Research Clinic. Payments will be made at the first visit, at the second visit after 4 weeks, and at the final visit after 8 weeks if you complete the entire study. The total payment you may receive is $100. If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit). If you are not chosen to participate in one of the intervention groups, you will not be paid.

New Findings
You will be told by Dr. Christy or the study staff if new information becomes available that might affect your choice to stay in the study.

Optional:

We would like your permission to take photographs and videos of you and your child as you complete the tests and interventions. The digital files will only be used for publications in scientific journals or for teaching at scientific conferences and professional medical continuing education courses. The digital files will be stored on a secure server at UAB. You can take part in this study even if you decide not to let us take pictures or videos.

Please initial your choice below:

_____ I agree to let the study team take pictures/videos of me and my child for the purposes mentioned above.

_____ I do not agree to let the study team take pictures/videos of me and my child for the purposes mentioned above.

If you agree, we will also ask you to sign a release form for this purpose.

Questions
If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact Dr. Jennifer Christy. You may contact Dr. Christy at 205-934-5903.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights
You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Legally Authorized Representative Date

_____

Signature of Person Obtaining Consent Date

Waiver of Assent

The assent of _____ (name of child/minor) was waived because of:

Age _____ Maturity _____ Psychological state of the child _____