

ASSENT FORM

TITLE OF RESEARCH: Feasibility of a Home-Based Vestibular Balance Therapy Intervention for Children with Vestibular Hypofunction

IRB PROTOCOL: IRB-300010569

INVESTIGATOR: Jennifer Christy, PT, PhD

SPONSOR: Foundation for Physical Therapy Research

The investigator named above is doing a research study.

These are some things we want you to know about research studies:

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things.

Whether or not to be in this research is your choice. You can say Yes or No. Whatever you decide is OK. We will still take good care of you.

Why am I being asked to be in this research study?

You are being asked to be in the study because you are a child with hearing loss and you can read story books or identify pictures from a computer.

What is the study about?

We want to see how the inside of your ear is working. To do this we will test how your eyes move when your head is moving. We also want to see how well you balance while you are standing still or walking. We also want to teach you and your parent some exercises.

What will happen during this study?

If you agree to be in this study, you will first visit the study doctor who will ask you to:

- Look at a sticker on the wall as the tester moves your head quickly to the side, up and down. Your eye movements will be measured by a camera that is on goggles that you will wear.
- Sit in a chair and put on goggles like a swim mask. You will be in the dark but will be talking to and listening to the tester. You will be asked to look at and follow a red dot with your eyes and look straight ahead as we rotate the chair slowly.
- Let us put stickers on your neck and an earphone in your ear. You will turn and lift your head as the earphone clicks in your ear.
- Let us put stickers under your eyes and a headband on your head that will shake. You will look up as the headband shakes a little.

Then you will go to the physical therapist who will ask you to:

- Wear a soft head band and tell us which way a letter “E” is facing. The “E” will appear on a computer screen. You will do this with your head still and while the tester moves your head like you are saying “No.”
- Stand as still as you can on a platform with your eyes opened and closed. The platform and walls might move a little during the test.
- Walk back and forth down a hall as you do different activities such as moving your head, walking heel-toe, walking backward, walking with eyes closed.
- Identify balance activities that you would like to be able to do better.

If you need to do the exercises, we will teach you and an adult who lives with you to do the exercises at home, 5 days per week, 20 minutes per day. To do the exercises, you will:

- Read aloud story books or tell us what pictures you see from the computer while an adult moves your head like you are saying yes and no.
- Walk down the hall and turn your head to look at pictures on the walls.
- Do balance exercises while you stand still, like standing on one foot or standing on thick foam.
- Do balance exercises while you are walking, like walking heel to toe or walking while you are turning your head.

If you do not need to do the exercises, we will ask you to do 2 things, 5 days per week:

- Read a book or look at pictures for 10 minutes
- Active play for 10 minutes

The physical therapist will work with you and your parent every week to be sure everything is going OK. After you do the exercises for 4 weeks, and after 8 weeks you will go back to the physical therapist to do the tests again.

Will the study hurt?

None of the tests will hurt. You might get a little dizzy when your head is being turned but you can let the adult know and they can stop. You might have some redness on your face from the goggles during the test, or redness on your skin from the stickers. You also might get tired from doing the exercises or lose your balance during the tests or exercises.

What else should I know about the study?

If you feel sick or afraid that something is wrong with you, tell an adult at once. You do not have to answer any questions that are asked of you or do any of the tests or exercises if you do not want to.

What are the good things that might happen?

People may have good things happen to them because they are in a research study. These are called “benefits. You might not benefit from being in this study.

What if I don’t want to be in this study?

You do not have to be in the study if you do not want to. If you don't want to be in this study, you can continue to get your medical care at Children's of Alabama.

Who should I ask if I have any questions?

If you have any questions about this study, you or your parents can call Dr. Jennifer Christy at (205) 934-5903.

Do I have to be in the study?

No, you do not have to be in the study. Even if you say yes now, you can change your mind later. It is up to you. No one will be mad at you if you don't want to do this.

Signatures

Before deciding if you want to be in the study, ask any questions you have. You can also ask questions during the time you are in the study.

If you sign your name below, it means that you agree to take part in this research study.

Child Participant Name (Printed)

Age

Child Participant Signature

Date

Signature of Person Obtaining Consent

Date

Signature of Witness

Date