

Study Title: The impact of hearing loss severity on balance intervention outcomes

PI (researcher): Caitlin N. Price

Institution: UAMS

## **Key Information for The Impact of Hearing Loss Severity on Balance Intervention Outcomes**

This first part gives you key information to help you decide if you want to join the study. We will explain things in more detail later in this form.

We are asking if you want to volunteer for a research study about hearing loss and risk of falls in older adults. By doing this study, we hope to learn how the A Matter of Balance program affects your balance and risk of falls and how hearing loss may be related to this.

Please ask the research team if you have any questions about anything in this form. If you have questions later, contact the researcher in charge of the study. The contact information is on page 9 of this form.

### **What will happen if I join the study?**

During the study, we will ask that you:

- Complete a hearing and balance test
- Answer some questions about:
  - Your background and health history
  - Your thoughts about potential falls and how this impacts you
  - Your current physical activity level
- Participate in the A Matter of Balance Program, an evidence-based program that includes group discussion, activities, and exercises to reduce fall risk
- Complete another balance test

If you join, your part in this research will last about 1 month. The initial visit for the hearing and balance test will last about 1-2 hours. The A Matter of Balance program will meet twice a week for a month. Each session will last about 2 hours.

### **Do I have to join this study?**

No. It is okay to say no. You will not lose any services, benefits, or rights you would normally have if you decide not to join. You can still participate in the A Matter of Balance program no matter what you decide about participating in the study. If you decide to take part in the study, it should be because you really want to volunteer.

### **What do I need to know to decide if I should join this study?**

People decide to join studies for many reasons. Here are some of the main things you should think about before choosing to join this study.

#### **Main reasons to join the study**

- ✓ Potential health benefits
  - ✓ Increased physical activity and exercise provided in the sessions
  - ✓ Better understanding of preventing and managing falls

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- ✓ More confidence about not falling

#### **Main reasons not to join the study**

- ✓ **Time commitment:** You should plan on attending at least 5 of the 8 sessions of the A Matter of Balance (AMOB) program. You may find it inconvenient to attend the AMOB sessions at the church or the study visits on the UAMS campus.
- ✓ **Possible exercise related injury:** The A Matter of Balance program includes light to moderate exercise. Modifications for exercises will be provided to accommodate individuals of all skill levels, and those participating will be encouraged to not push beyond their comfort zone and stop exercising if any pain or discomfort is experienced.

These are just some of the reasons to help you decide if you want to join the study. We will explain more about the risks, benefits, and other options to joining the study later in this form.

Tell the study team if you decide that you do not want to be in the study. Remember, it is okay to say no. You can still get your medical care from UAMS if you are not in the study.

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## University of Arkansas for Medical Sciences Informed Consent Form

- **We are asking you to be in a research study. You do not have to join the study.**
- **You can still get your medical care from UAMS even if you are not in the study.**
- **Take as much time as you need to read this form and decide what is right for you.**

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

- We want to learn more about how hearing loss relates to someone's risk of falling and how we can better help older adults who are at greater risk of falling.
- By doing this study, we hope to find out whether the A Matter of Balance program helps people improve their balance.
- We are asking people like you, who have concerns about falling, to help us.
- Thirty-six adults 60 and older will be part of this study.

### What if I don't understand something?

- This form may have words you do not understand. If you would like, research staff will read it with you.
- You are free to ask questions at any time – before, during, or after you are in the study.
- Please ask as many questions as you would like before you decide if you want to be in this study. If you decide to take part in the study, it should be because you really want to volunteer.

### What will happen if I say yes, I want to be in this study?

First, we will see if you qualify to be in the study by asking you some questions about your health history.

If you qualify, we will do these things:

- Ask about your health, what medicines you take, and if you exercise
  - Based on your answers, you may need to talk to your doctor before starting the exercises included in the A Matter of Balance program.
- Ask you to complete questionnaires about your risk of falling and how you feel about falls. The questionnaires should take you about 30 minutes to complete.

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- Read the questions out loud and fill out the form with you, if you like.
- You do not have to answer any questions you do not want to answer.
- Have your hearing and balance tested
  - The hearing and balance tests are used routinely in audiology offices.
  - For the balance test, you will be asked to try to keep your balance for 20 seconds at a time (done 4 times with breaks in between) while standing on a balance plate. This plate looks like a scale but does not measure your weight.
    - The first time will be a practice trial to give you an example.
    - To avoid the risk of falling during the balance test, trained staff will surround you and provide support if needed.
- Complete the A Matter of Balance Program by attending at least 5 of the 8 sessions
  - This is an evidence-based program that includes group discussion, activities, and exercises to reduce fall risk.
  - Each session focuses on a different topic related to falls and most sessions (starting with the 3<sup>rd</sup> session) include physical exercises.
    - Class topics include concerns about falling, how exercise and physical activity reduces fall risk, how to prevent falls, common habits that increase fall risk, and fall hazards in your home and community
    - Physical exercises include both seated and standing exercises to improve strength, coordination, and physical endurance. Examples of exercises are arm and wrist exercises like arm presses, wrist rotation, and arm chair push ups and leg exercises like leg extensions, heel and knee raises, marching in place, and hip and foot circles.
      - All standing exercises require participants to hold on to a chair to increase stability and minimize fall risk.
      - We will show you how to complete standing exercises while staying seated, if needed.
  - Repeat the balance test
  - Complete the same questionnaires about your risk of falling and how you feel about falls.



If you join, your part in this research will last about 1 month. The initial visit for questionnaires and the hearing and balance (risk for falling) test will last about 1-2 hours. The A Matter of

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Balance program will meet twice a week for a month. Each session will last about 2 hours. You will be asked to complete the final questionnaires and balance test during your last session of A Matter of Balance. This should take about 30-45 minutes to complete.

### **How long will I be in this study?**

You will be in the study for about 1 month. It will include 9-10 visits. The first visit will include the hearing and balance tests and questionnaires. The rest of the visits will include the A Matter of Balance sessions that will happen twice a week for a month (8 visits). Each session will last about 2 hours. If the final balance test is not completed at the final A Matter of Balance session, then an appointment to complete this may be scheduled at a more convenient time (10<sup>th</sup> visit).

### **What if I say no, I do not want to be in this study?**

- Nothing bad will happen because of what you decide.
- You can still get medical care at UAMS.
- You can still participate in the A Matter of Balance program.

### **What happens if I say yes but change my mind later?**

- You can stop being in the study at any time.
- Nothing bad will happen because you change your mind and leave the study.
- You can still get medical care at UAMS.
- You can still participate in the A Matter of Balance program.
- If you decide to stop being in the study, let someone on the study team know.
  - If you decide you do not want your information that has already been collected to be included in the study, your information can be removed until data collection has been completed (after the final balance test). After this time, you will not be able to withdraw your information from the study.

### **Will it cost me anything to be in the study?**

The study will not cost you anything.

### **Will I be paid for being in the study?**

Yes. We will give you a \$50 Kroger gift card. This is to pay for your time. You will receive your gift card at the end of the study. If you change your mind and decide not to be in the

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study, you will only be paid for the parts you completed (\$10 per research visit and \$6 per intervention session up to the full \$50). Participants will not be charged parking fees for the research visits.

If you get more than \$600 in one year (January-December) from UAMS, we may send you a tax form if the law requires it.

### **Will being in this study help me in any way?**

Being in the study may or may not help you, personally. But even if it does not help you, it may help people with hearing and balance problems in the future. What we learn may help in the following ways:

- It may help us better understand the impact of balance intervention programs.
- It may help us see whether and how hearing loss is related to balance problems or the benefit of balance interventions.

### **What are the risks of being in this study?**

The risk of joining this study is:

- Possible exercise related injury
  - The A Matter of Balance program includes light to moderate exercise. Modifications for exercises will be provided to accommodate individuals of all skill levels. Those participating will be encouraged to not push beyond their comfort zone and stop exercising if any pain or discomfort is experienced. Because of this, the likelihood of these injuries happening is small, but some soreness lasting a couple of days is possible.

There is also the risk that someone could find out that you were in the study and learn something about you that you do not want others to know. We will do our best to protect your privacy, as explained in more detail later in this form.

### **What if I get hurt while I am in this study?**

- If you get hurt when you are here for the study, we will help you get the care you need. This may include first aid, emergency care, and any follow-up care you need.
- This treatment will be billed to you or your insurance company. No other form of payment is available.

**Reminder:** You do not give up any of your legal rights by agreeing to be in this study or by signing this form.

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### **What are the alternatives to being in this study?**

You do not have to be in this study.

If you decide not to join this study, you have the following option:

- You can participate in the A Matter of Balance Program without joining the study.
- Talk to your doctor or an audiologist about your concerns about falling. They may have additional recommendations based on your specific health and balance needs.

### **Can I be taken out of the study even if I want to continue?**

Yes, the study head researcher can take you out of the study if:

- You do not follow study instructions.
- It is not in your best interest to continue.

### **What information will be collected about me in the study?**

During the study, we will need to learn private things about you, including

- General background information about you, such as your gender, race, ethnicity, and household status
- Medical information about you, such as your feelings of your general health, previous health or medical conditions, current medications, and hearing and balance information
- Personal information, such as your feelings of your general health, social and physical activity levels, your thoughts about potential falls and how this impacts you

This information will be collected using questionnaires and discussions with a member of the study team.

### **Who will see this information? How will you keep it private?**

- The local study team will know your name and have access to your information.
- We will do our best to make sure no one outside the study knows you are part of the study.
- We will take your name off information that we collect from you during the study. We will give your information a code, so that no one can identify you.
- When we share the results of the study at professional conferences or in academic journals, we will not include your name or anything else that could identify you.

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- State law requires that we tell the authorities if we learn about possible abuse or that you might hurt yourself or someone else.

### **Where and for how long will my information be kept?**

- Your information will be labeled using a code and kept in a locked office.
- Once we give your information a code, we will keep the key to this code (which includes your identifying information) in a locked file.
- At the conclusion of the study, all project information, reports, and analyses will be retained for at least seven years per UAMS policy.
  - If you decide to consent for your information to be used in future studies, the information will be deidentified and stored in an Excel spreadsheet indefinitely.
  - If you do not wish for your information to be used in any future studies, the information will be destroyed after seven years.
  - At the end of data collection (once all participants have finished their final balance test), the file with participants' assigned codes will be destroyed.
- We will not put information about you from the study in your medical record.

### **If I stop being in the study, what will happen to my information collected in the study?**

- We will be able to take your information out of the study after it has started, but only until the end of data collection. Once everyone from the study has completed their final balance test, you will no longer be able to have your information removed from the study.
- If you wish to have your information taken out of the study before it is deidentified, call Dr. Caitlin Price, the primary researcher for the study, at (501) 686-8125.

### **Will my information from the study be used for anything else, including future research?**

Yes. If you agree below, we may use your information collected in this study in larger scale studies on hearing and balance problems in older adults or other studies with the goal of answering related research questions.

- The information we will be collecting will allow us to answer many questions about the assessment and treatment of older adults with hearing and balance concerns. Because of this, we may use your information later by using it to answer different questions than the ones described here. These questions may include topics like:
  - Do individuals who use hearing aids benefit differently from balance interventions?
- We may also collect additional information from other groups of people (for example, people with diagnosed balance disorders or severe vision impairment). In this case, your information (along with others) may be included to serve as a comparison.

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- If you agree for your information to be used in future studies, your information will be stored indefinitely in a password protected spreadsheet and only individuals on the study team will have access to this information. None of the information retained for future research will include any identifying information linking the information to you. Because the information will be anonymous, we will not be able to remove your information after the document including participant codes has been destroyed (following data collection for this study).
  - To request removal of your data from future use before it is deidentified, you may contact Dr. Caitlin Price at (501) 686-8125.

### **Will you tell me the results of the study?**

If participants are interested in our findings, we can share this information at a later time.

### **Will you tell me anything you learn that may affect my health?**

Yes. If we learn something about you that might be important for your health, we will tell you and give you appropriate resources for follow-up care if necessary.

### **What if new information comes up about the study?**

We will tell you if we learn anything that may change your mind about being in the study.

### **Where can I find more information about this clinical trial?**

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 you. At most, the website will include a summary of the results. You can search this website any time.

### **What if I have questions?**

- Please call the head researcher of the study, Dr. Caitlin Price, at (501) 686-8125 if you
  - ✓ have any questions about this study
  - ✓ feel you have been injured in any way by being in this study
- You can also call the office at UAMS that supervises research if you cannot reach the study team, have questions about your rights as a research participant, or want to speak to someone not directly involved with this study. To do so, call the UAMS Institutional Review Board at 501-686-5667 during normal work hours.

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**By signing the document, I am saying:**

- I agree to be in the study.
- I know that joining this study is voluntary.
- Someone has talked with me about the information in this form and answered all of my questions.

**I know that:**

- I can stop being in any and all parts of the study at any time and nothing bad will happen to me.
- I can still get medical care at UAMS no matter what I decide.
- I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- I do not give up any of my legal rights by signing this form.

**I agree to be part of this study:**

\_\_\_\_\_  
Your name (please print)

\_\_\_\_\_  
Your signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name (person obtaining consent)

\_\_\_\_\_  
Signature (person obtaining consent)

\_\_\_\_\_  
Date

**My information collected in this study may be used in future research.**

\_\_\_\_ Yes      \_\_\_\_ No

\_\_\_\_\_  
Your name (please print)

\_\_\_\_\_  
Your signature

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**I agree to be contacted for future hearing and balance research related to this study.**

YES       NO

Preferred method of contact (telephone/email): \_\_\_\_\_

\_\_\_\_\_  
Your name (please print)

\_\_\_\_\_  
Your signature

\_\_\_\_\_  
Date

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### **HIPAA Research Authorization**

For our study, we will need to get health information about you including information about your health conditions, exercise, drug and alcohol use, balance and hearing, and your response to the balance program. You may also do some study activities that produce new health information about you (hearing and balance test results). To join this study, we need your permission to collect, create, and share this information.

The information from this study (including information that identifies you) may be shared with or accessed by people who make sure the study is run the right way. This includes people from the Federal Office for Human Research Protections, the UAMS Institutional Review Board, and other institutional oversight offices. We think everyone involved with research understands how important it is to keep your health information private. But people outside UAMS may not follow the same laws that UAMS follows to protect your health information.

When you sign this form, you agree to let us collect, produce, and share health information about you as we describe in this form. Your authorization ends 5 years after we have finished presenting this study's results.

You do **not** have to sign this form. **But, if you do not sign it, you cannot be in the study.** If you decide not to be in the study, it will not affect the care or benefits you get from UAMS.

#### How to withdraw your HIPAA authorization

If you sign this form and decide later that you do not want us to use your health information for the research, you must send a letter to the Principal Investigator, Dr. Caitlin Price, at 4301 W. Markham St., Slot #711, Little Rock, AR 72205. In your letter, include:

- The study title (from the top of this form)
- A statement saying you changed your mind and are ending your "HIPAA Research Authorization"
- Your signature

After we get the letter, we will take you out of the study and stop collecting your health information. But we may still use and share your health information we collected before we got your letter. If you quit the study, it will not change your care or benefits from UAMS.

Researchers and staff can collect health information about \_\_\_\_\_ and use it for the study described here and in the research consent form.

\_\_\_\_\_  
Your name (please print)

\_\_\_\_\_  
Your signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship to participant