UNIVERSITY OF SOUTH FLORIDA

Informed Consent to Participate in Research and Authorization to Collect, Use, and Share your Health Information

Information to Consider Before Taking Part in this Research Study

Title: ***Assessment of e-Audiology for providing clinical services and supports for age-related hearing loss: A pilot study***

Pro # 00041124

Overview: You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is being led by Dr. Michelle Arnold who is a researcher at the University of South Florida (USF). This person is called the Principal Investigator. Other approved research staff may act on behalf of the Principal Investigator.

Study Details: This study is being conducted at USF in Tampa, FL. The purpose of the study is to find out how adults with hearing loss prefer to receive hearing aid services, and what the outcomes are when hearing aid services are delivered over the internet.

Participants: You are being asked to take part because you are an adult with hearing loss who is a candidate for hearing aids and hearing aid services.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Alternatives to participating in the study include: seeing a hearing healthcare professional and receiving hearing aids in a non-research setting.

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. There is no cost to participate. You will be able to keep any hearing aids you receive as part of your participation in this study. This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life. The most common and most serious risks that may be related to taking part in this research include boredom, minor irritation, or minor fatigue when completing the study tasks. You might also experience slight discomfort from the study procedures for hearing testing and hearing aid fitting.

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

Why are you being asked to take part?

This study includes the use of hearing aids for the treatment of hearing loss. The hearing aids used in this study are manufactured by a company called Phonak, and are approved by the Food and Drug

Administration (FDA) for the treatment of hearing loss. Hearing aids are being used as part of this research study to find out what outcomes adults experience when they receive their hearing aid services over the internet.

Study Procedures: What will happen during this study?

In this study, you will be asked to have a hearing test and complete some questionnaires. Then, you will be fit with two hearing aids which you will wear on a daily basis. All of your follow-up visits will be delivered over the internet, using your own smart device, such as a smart phone, tablet, or computer. You will be asked to remain in the study for 6 months. The list below gives details about what will happen at each visit.

- Baseline visit: Your first visit is the baseline visit. You will complete the informed consent document. If you agree to participate, you will then complete a memory screening, a vision screening, and a hearing test. If you meet the eligibility requirements for the study, you will then complete some questionnaires and have a hearing aid fitting. Following the hearing aid fitting, the researcher will teach you how to care for the hearing aids, and answer any hearing aid questions you have. This visit will take about 2 to 3 hours.
- Follow-up visits: You will be asked to attend follow-up visits at least once every 2 weeks over the course of 6 weeks. Each follow-up visit will occur over the internet using your own smart device. The follow-up visits will include hearing aid fine-tuning and help with difficult listening situations you have, or addressing any hearing or hearing concerns you have. After each follow-up visit, you will be asked to complete a questionnaire asking you about your satisfaction with the visit with a research assistant. Each follow-up visit will take about 30 to 60 minutes
- Outcomes visit: The outcomes visit will take place about 6 weeks from today in this lab. You will be asked to complete some hearing tests with your hearing aids on. You will also be asked to complete some questionnaires, and take part in a recorded interview. Only approved research personnel will be allowed to audio record your interview, and only approved research personnel will have access to your recording. We might quote some of your interview in print, but your voice will not be used, nor will your identity be revealed if we use any part of your recording. The recordings will be maintained on a password-protected, HIPAA-compliant server for up to 5 years, and will be destroyed using USF standard operating procedures for erasing digital media.
- 6-month follow-up: We will track you for 6 months (about 1 time each month) following the outcomes visit to determine how much additional support you need with your hearing aids, such as repair needs, programming tune-ups, etc. This contact will take place either over the phone, a smart device, or in person, which will be your choice.

Total Number of Participants

About 20 individuals will take part in this study at USF.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study. Alternatives to participating in the study include: seeing a hearing healthcare professional for hearing aids in a non-research setting of your choice.

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this

study.

You can decide after signing this informed consent document that you no longer want to take part in this study for any reason at any time. If you decide you want to stop taking part in the study, tell the study staff as soon as you can. If you decide to stop, you can continue getting care from your regular audiologist, or we will help you find an audiologist to continue care in a non-research setting.

Please note, even if you want to stay in the study, there may be reasons we will need to withdraw you from the study. You may be taken out of this study if we find out it is not safe for you to stay in the study or if you are not coming for the study visits when scheduled. We will let you know the reason for withdrawing you from this study.

Benefits

The potential benefits of participating in this research study include:

- Better understanding of your hearing loss
- Improved communication function as a result of using hearing aids
- Decreased frustration when trying to communicate as a result of using hearing aids

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study. However, you may experience some minor boredom, frustration, or fatigue at the study visits, which are similar to those you would experience at your normal doctor's office. You may experience slight discomfort as a result of some of the hearing testing or hearing aid fitting procedures, which are the same if you received hearing aids in a non-research setting.

Compensation

You will be able to keep the hearing aids you receive if you complete all the scheduled study visits. You will receive no payment or other compensation for taking part in this study.

Costs

It will not cost you anything to take part in the study, but you are responsible for your own transportation to and from the study visits, as well as any costs accrued as a result of using your own smart device during your time in this study.

Privacy and Confidentiality

We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may need to see your study records. These individuals include:

- The research team, including the Principal Investigator, study coordinator, research assistants, and all other research staff.
- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.

- Any agency of the federal, state, or local government that regulates this research. This includes the Department of Health and Human Services (DHHS) and the Office for Human Research Protection (OHRP).
- The USF Institutional Review Board (IRB) and its related staff who have oversight responsibilities for this study, and staff in USF Research Integrity and Compliance.

Your information or samples collected as part of the research, even if identifiers are removed, will NOT be used or distributed for future research studies.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

Although the technology we use to deliver services over the internet is secure, it is possible, although unlikely, that unauthorized individuals could gain access to your information. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this study involves risks similar to a person's everyday use of the Internet.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in this study. We will notify you as soon as possible if such information becomes available.

We may learn things about you from the study activities that could be important to your health or to your treatment. If this happens, this information will be provided to you. The type of information we will provide will be hearing testing results. The results will not be placed in your medical record. You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call Dr. Arnold at 813-974-1262. If you have questions about your rights, complaints, or issues as a person taking part in this study, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting the University of South Florida to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than USF who are also involved in the research and listed below.

In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research:

- The medical staff that takes care of you and those who are part of this research study;

- Each research site for this study including USF;
- The USF Institutional Review Board (IRB) their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research.

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, USF may collect, use, and share the following information

- Your research record
- All of your past, current or future medical and other health records held by USF, other health care providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to records related to HIV/AIDs, mental health, substance abuse, and/or genetic information.

You can refuse to sign this form. If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke your authorization at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

- You will no longer be a participant in this research study;
- We will stop collecting new information about you;
- We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
- Staff may need to follow-up with you if there is a medical reason to do so.

To revoke your authorization, please write to:

Principal Investigator
For IRB Study # 00041124
University of South Florida
Auditory Rehabilitation and Clinical Trials Lab
4202 E. Fowler Ave. PCD 1017
Tampa, FL 33620

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies.

Consent to Take Part in Research and Authorization for the Collection, Use and Disclosure of Health Information

I freely give my consent to take part in this study and authorize that my health information as agreed above, be collected/disclosed in this study]. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

_____ _____

Signature of Person Taking Part in Study Date

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Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent and Research Authorization

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research participant speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research participant has provided legally effective informed consent.

_____ _____

Signature of Person Obtaining Informed Consent Date

_____

Printed Name of Person Obtaining Informed Consent