Official Title of the study: Impact of Hearing Aid Service-delivery Model and Technology on Patient Outcomes: A Randomized Clinical Trial

NCT number: NCT03579563

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Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Todd A. Ricketts **Revision Date: 10/05/18**
Study Title: Cost-effective hearing aid delivery models
Institution/Hospital: Vanderbilt University Medical Center

This informed consent document applies to adults with hearing loss aged 55-85.

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in this research study is voluntary. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study. The National Institute on Deafness and other Communication Disorders (NIDCD) is funding this research study.

1. Purpose of the study:
The purpose of this research study is to compare characteristics of new hearing aid users to various models of hearing aid delivery in order to help develop guidelines and instruction materials for consumers on which avenue of amplification to pursue. You are being asked to participate because you are a potential hearing aid candidate that has not yet tried hearing aids. Approximately 300 people are expected to be recruited for this study at Vanderbilt and the University of Iowa

2. Procedures to be followed and approximate duration of the study:
If you agree to take part in this study, your involvement will last for 4 to 6 research visits lasting no longer than 2.5 hours each plus a 7 week long hearing aid field trial. Total study time for you should be approximately 2 months.

If you consent to participate in this study, we will first test your hearing, during which you will be asked to respond to sounds played through headphones. After the hearing screening, if you are eligible to continue and are not tired we will have you remain in the sound room and we will test your ability to understand speech in background noise. Speech and noise will play through loudspeakers in the room and you will repeat as much of it as you can.

Next, we will measure your personal characteristics that may impact hearing aid use. We will do a cognitive screening by having you name, draw, repeat and memorize items. We will test your working memory by having you read groups of sentences and we'll ask you to try to remember as many of the first words or last words of each sentence in the group. Next we will test your manual dexterity by having you put pegs into and remove them from a board with each of your hands.

You will complete multiple paper and pencil questionnaires assessing your hearing without amplification, personality, quality of life, and locus of control.

In this study you will also be asked to take surveys delivered by a smartphone app (either on your personal phone or one provided by the laboratory) as you go about your daily listening activities for a week before your hearing aid intervention and for a week at the end of the hearing aid trial. The smartphone app will deliver surveys randomly throughout the day (approximately one every hour and a half) during a time window that you will specify. The survey questions will ask you if some common listening experiences have happened in the recent past and will ask you to describe them. You will be trained on how to use the smartphone app (and smartphone if necessary) before leaving the lab. Next we will send you out for one week to assess how you hear in the real world without any amplification.

In one week you will return for the second visit. At this visit you will be fitted with hearing aids. Next, you will fill out a questionnaire on how you expect the hearing aids will impact your life.

The next part of the study is a 7-week field trial with the study hearing aids that we will provide. You will be asked to return the hearing aids to us at the end of the study. Study hearing aids cannot be purchased through the laboratory, but are commercially available.

After you have used the hearing aids for six weeks we will have you return to the laboratory. At that visit we will configure the smartphone app to deliver surveys for your aided assessment week. We will also take some measurements of the hearing aids' features while you wear them and test your ability to hear in noise with the hearing aids. Next we will send you out into the real world to assess how you hear with the hearing aids.

You will return to the lab one week later to complete the study. At that research visit we will have you fill out more questionnaires based on how you hear with the study hearing aids. When filling out the questionnaires we would like you to answer based on the intervention services and ignore the pre-intervention testing. We will also test your ability to manipulate and use the hearing aids. We will end with interviewing you about your experience with the hearing aids, debriefing you about the other service delivery models and answering any questions you have about your hearing.

3. Expected costs:
There are no expected costs to you for participating in the study.

4. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:
The risks and inconveniences to being in the study are expected to be minor. First, there is the potential for loss of confidentiality which is minimal due to secure data storage and the types of data being collected. The second risk is boredom during the test session. To minimize boredom, you can take breaks as needed during testing. Third, there is a risk that the surveys may cause inconvenience to your typical day. To minimize these risks, you can stop taking a survey at any time and are not required to complete all surveys. Do not complete a survey if you are in an unsafe environment or are participating in another activity simultaneously (e.g., driving).

5. Compensation in case of study-related injury:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

6. Good effects that might result from this study:
a) The benefits to science and humankind that might result from this study are a better understanding of how service affects hearing aid users' experiences.
b) There are no direct benefits to you from this study.

7. Compensation for participation:
You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you when compensation is $100 or more. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide

your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will be paid $7.50 per half hour of study research time, excluding time related to hearing aid intervention. The total amount of non-intervention research visit time will be approximately 7 hours, for a total of $105. We will process payment when you complete your participation and you should receive payment approximately 6-8 weeks later.

If you decide to withdraw from the study you will be paid for the non-intervention research time you have completed. If you do not qualify for this study you will not receive compensation.

8. Circumstances under which the Principal Investigator may withdraw you from study participation:
We may withdraw you from the study if we feel you cannot complete the test procedures within an appropriate time frame. Your data will be kept if you are withdrawn from this study, but we will destroy it if you ask us to. If we have to withdraw you from the study we will tell you why.

9. What happens if you choose to withdraw from study participation:
Your participation in this research study is voluntary and you are free to withdraw from this study at any time. Just let me know if you want to stop. Withdrawal or refusal to participate will not prejudice you in any way. Should you choose to withdraw you will be compensated for the time completed. Your data will be kept if you withdraw from this study, but we will destroy it if you ask us to.

10. Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact **Todd Ricketts** at **(615) 936 – 5100.** For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the **Vanderbilt University Institutional Review Board Office** at **(615) 322-2918 or toll free at (866) 224-8273.**

13. Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. The data we will collect consists of hearing aid gain values, thresholds, speech understanding scores and survey results. We will keep hard copies of these data in a locked laboratory. An electronic copy of the same data will be coded using a number rather than your name and stored on a password protected computer. Both the hard copy and the electronic data are located in the Dan Maddox Hearing Aid Research Laboratory which remains locked if research personnel are not present. We will keep these research results indefinitely.

To help protect your confidentiality, we will use only subject codes as identifiers on data sheets, secure all files in locked cabinets/rooms, and use password-protected computer files. The list linking your study subject code and your name will be stored in a secure location that is accessible only to the investigators. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

14. Certificate of Confidentiality:
This study may have support from the National Institutes of Health. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

15. Privacy:
Your information may be shared with Vanderbilt or the government, such as the Vanderbilt University Institutional Review Board, Federal Government Office for Human Research Protections, or the National Institute on Deafness and Other Communication Disorders (the sponsor), if you or someone else is in danger or if we are required to do so by law.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

INFORMED CONSENT DOCUMENT

Project Title: **Hearing aid outcomes**

Principal Investigator: Yu-Hsiang Wu

Research Team Contact: **Yu-Hsiang Wu, M.D., Ph.D., Elizabeth Stangl, Au.D. (319) 335-9758**
uiowa-hal@uiowa.edu

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to explore possible benefits from using hearing aids..

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 200 people will take part in this study conducted by investigators at the University of Iowa. Approximately 200 people will take part in the same study conducted by investigators at Vanderbilt University in Nashville, TN.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 4 to 6 research visits lasting no longer than 2.5 hours each plus a 7 week long hearing aid field trial. Length of participation should last approximately 2 months.

WHAT WILL HAPPEN DURING THIS STUDY?

If you consent to participate in this study, we will first assess your hearing. You will be given a hearing test during which you will be asked to respond to sounds through headphones. After the hearing screening, if you are eligible to continue and are not tired we will have you remain in the sound room and we will test your ability to understand speech in background noise. Speech and noise will play through loudspeakers in the room and you will repeat as much of it as you can.

Next, we will measure your personal characteristics that may impact hearing aid use. We will do a cognitive screening by having you name, draw, repeat and memorize items. We will test your working memory by having you read groups of sentences and we'll ask you to try to remember as many of the first words or last words of each sentence in the group. Next we will test your manual dexterity by having you put pegs into and remove them from a board with each of your hands.

You will complete 15 questionnaires assessing your hearing, personality, quality of life, memory and other information that may be helpful for the study.

In this study you will also be asked to take surveys delivered by a smartphone app on a smartphone provided by the laboratory as you go about your daily listening activities for a week before your hearing aid intervention and during the last week of the hearing aid trial. The smartphone app will deliver surveys randomly throughout the day (approximately one every hour and a half) during a time window that you will specify. The survey questions will ask you if some common listening experiences have happened in the recent past and will ask you to describe them. You will be trained on how to use the smartphone app (and smartphone if necessary) before leaving the lab. You will return the smartphone to the lab after each assessment week.

Next we will send you out for one week to assess how you hear in the real world without any amplification.

In one week you will return for the second visit. Your hearing aid intervention will then begin. You will be provided with a pair of study hearing aids that you will return at the end of the study, and you will also fill out a questionnaire on how you expect the hearing aids will impact your life.

The next part of the study is a 7-week field trial with the study hearing aids. After you have used the hearing aids for six weeks we will have you return to the laboratory. At that visit we will configure the smartphone app to deliver surveys for your aided assessment week. We will also take some measurements of the hearing aids' features while you wear them and test your ability to hear in noise with the hearing aids. Next we will send you out into the real world to assess how you hear with the hearing aids.

You will return to the lab one week later to complete the study. At that research visit you will return the study hearing aids and the smartphone. We will have you fill out more questionnaires based on how you heard with the study hearing aids. We will also test your ability to manipulate and use the hearing aids. We will end with interviewing you about your experience with the hearing aids, and answering any questions you have about your hearing. The interview will be recorded, but you may opt out of it if you do not wish to be recorded.

Audio Recording

One aspect of this study involves making an audio recording of the final interview. The audio will be used to ensure that we do not miss any information you provide about your study experience. The recordings will be reviewed to obtain qualitative data about your hearing aid experience. The recordings will be made by a digital recorder in the Hearing Aid and Aging Research Lab.

The investigator and research team will use a password-protected computer to review the recording. If you don't want a (or parts of the) recording to be analyzed, the research team will not analyze it and the recording will be deleted permanently.

You may still be in the study if you do not wish to be audio recorded.

[ ] Yes [ ] No I give you permission to audio record the study's final interview.

Data Storage for Future Use

As part of this study, we are obtaining data from you. We would like to study your data in the future, after this study is over.

The tests we might want to use to study your data may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding the effectiveness of hearing aids, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your data, but decide in the future that you would like to have it removed from future research, you should contact Yu-Hsiang Wu, M.D., PhD, at 319-335-9758. However, if some research with your data has already been completed, the information from that research may still be used.

Please place your initials in the blank next to Yes or No for each of the questions below:

My data may be used for research.

_____ Yes _____ No

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

You may feel fatigue during the testing sessions in the laboratory. We will give you breaks between tests. Each visit will be no longer than two and a half hours. It is also likely that you may feel frustrated in some laboratory test environments in which there is background noise. It is normal to have difficulty recognizing soft speech in loud noise. There is also a risk of loss of confidentiality. Measures in place to protect confidentiality are noted in the 'What About Confidentiality' section later in this document.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study. However, we hope that in the future, others might benefit from the knowledge we hope to gain from it.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

It will not cost you anything for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you when compensation is $100 or more. You may choose to participate

without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will be paid $7.50 per half hour of study research time, excluding time related to hearing aid intervention. The total amount of non-intervention research visit time will be approximately 7 hours, for a total of $105. In addition you will be provided with vouchers to cover the cost of parking in the University Ramps.

If you decide to withdraw from the study you will be paid for the non-intervention research time you have completed.

WILL YOU KEEP MY NAME ON FILE TO GIVE TO OTHERS?

We will keep information about you in a special kind of computer listing called a registry. A registry keeps information about you on file so that *other* researchers, not involved in this particular study, may contact you in the future about whether you are interested in being in *different* research studies. The registry will contain information such as your name, address, age, and selected medical information such as diagnosis and treatment. We will keep the information in this registry secure by storing it on password protected computers in a locked office. You may request that your personal information be removed from this file at any time by contacting Yu-Hsiang Wu, M.D., Ph.D., 319-335-9758.

You may still participate in the research study even if you choose not to be in the registry.

[ ] Yes [ ] No I give you permission to put my name and personal information in a registry so that other researchers can contact me in the future about different research studies.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- The National Institute on Deafness and Other Communication Disorders (NIDCD)
- People who use the registry
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will use only subject codes as identifiers on data sheets, secure all files in locked cabinets/rooms, and use password-protected computer files. The list linking your study subject code and your name will be stored in a secure location that is accessible only to the investigators.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Yu-Hsiang Wu at (319-335-9758**.** If you experience a research-related injury, please contact: Yu-Hsiang Wu at (319-335-9758.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

FOR IRB USE ONLY
APPROVED BY: IRB-01
IRB ID #: 201804771
APPROVAL DATE: 10/16/22
EXPIRATION DATE: 10/16/23

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 10/16/23.

_____ _____
(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)