

Consent Form

Title of Research Study: *A system and process to improve the satisfaction with hearing health products*

Investigator Team Contact Information: Peggy Nelson

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Peggy Nelson Investigator Departmental Affiliation: Speech-Language-Hearing Sciences Phone Number: 612-625-4569 Email Address: peggynelson@umn.edu	Audiology team member Monica Andriacchi Phone Number: 612-624-3322
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Supported By: This research is supported by the National Institutes of Health.

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:
We have no financial interest to disclose.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

- The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being invited to take part in this research study?

We are asking you to take part in this research study because you may be interested in the study of hearing aid adjustment and health-related coaching for hearing loss. You were recruited as a possible participant because of your hearing status and your appropriateness for this type of technology

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.

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- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to learn how health coaching strategies might help hearing aid users adjust their hearing aids in daily life. Health coaching is a relationship-based, client-driven process of achieving goals. Coaches apply understanding and skills around to empower individuals to set and achieve their personal goals for optimizing their wellbeing.

How long will the research last?

We expect that you will be in this research study for about 3 months. You will be fit with the hearing aids, then followed by a health coach or audiologist. At the end of 3 months you will complete several surveys to determine changes that happened over the 3-month period.

What will I need to do to participate?

You will be asked to join either a coaching or a standard-of-care group. If in the coaching group, you will be matched with one coach for the duration of the study (barring any emergency situations.) Coaches will partner and support clients around whatever issues--physical, mental, emotional, spiritual or relational--that the client wishes to address, regardless of whether or not the issue appears to directly involve the hearing loss or hearing aid use. Content of the sessions is confidential, and will only be shared as generalized and de-identified information for the purposes of research. Coaches will have access only to summary level information about a client's hearing aid use from the system. Clients have total control over whatever else they choose share with the coach. If in the standard-of-care group you will be followed by an audiologist, as is current clinical practice.

More detailed information about the study procedures can be found under "What happens if I say yes, I want to be in this research?"

Is there any way that being in this study could be bad for me?

There is no reason the study could be bad for you.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, you will be followed by a hearing health professional as you adjust to listening with new hearing aids. More detailed information about the benefits of this study can be found under "Will being in this study help me in any way?"

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 60 people will be in this research study.

What happens if I say "Yes, I want to be in this research"?

The experimental treatment you get will be chosen by chance, like flipping a coin. Neither you nor the investigator will choose what experimental treatment you get. You will have a 50/50 chance of being given either standard-of-care or health coaching experimental treatment.

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If you agree to be in this study, we would ask you to do the following things:

If you have hearing loss, you will be fit with hearing aids by an audiologist, adjusting the hearing aids according to best audiological practices and your most recent hearing test results that you will provide to the study team. You will be asked to download an application (“app”) to your smartphone. You then may be asked to wear the hearing aids in actual quiet rooms and restaurants and to repeat the adjustments in a mobile application or “app”. You may be asked to judge the loudness of your own voice. You may be asked to use them in your daily environment for a month. You may be then asked to rate the hearing aids for their sound quality, comfort, and ease of listening. You may be asked brief survey questions about app usability, listening difficulty and sound quality as you use the devices at home.

Participants assigned to the health coaching arm of the study are asked to commit to a minimum of 4 virtual visits with their health coach over the duration of the study, but are free to schedule more sessions if they wish. The initial session will be 1 hour, and follow-up sessions will be 30-50 minutes. Participants will have reasonable control over the scheduling of sessions with their coach. Participants in the standard-of-care arm will be able to consult with an audiologist as needed during the same time frame.

Testing will occur at the first virtual visit following consent, and again at 3 months post-fitting.

If public health restrictions allow, you may be offered the option to come to the CATSS laboratory in Elliott Hall to listen in various kinds of noise that simulate quiet rooms and restaurants. You will be able to adjust your hearing aids to make listening in those environments most successful.

What happens if I say “Yes”, but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision. If you decide to leave the research study, contact the investigator

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

There are no risks to the study.

Will it cost me anything to participate in this research study?

There will be no cost to you for any of the study activities or procedures.

Will being in this study help me in any way? (Detailed Benefits)

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include learning the added value of health coaching to the process of hearing aid adjustment.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. If you have a health coach, they will have access to your hearing test results. We cannot promise complete confidentiality. Organizations that may

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inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you \$150 for your time and effort.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent