Effects of PSAPs on Speech Processing

NCT05076045

Consent Form

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Rotman Research Institute
Baycrest Health Sciences
3560 Bathurst Street
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Title of Project: Immediate Effects of Personal Sound Amplification Products on Speech Processing

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CONSENT FORM

INTRODUCTION

You are invited to participate in a clinical trial (a type of study that involves research). This study does not involve drugs and is not harmful to your health. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect current or future health care.

CONFLICT OF INTEREST

There are no conflicts of interest to declare related to this study.

PURPOSE OF THIS STUDY

The purpose of this study is to investigate how the immediate use of *personal sound amplification products* affects how the brain processes auditory information. This study involves two three-hour visits separated by one week.

During the two visits, you will be asked to complete questionnaires and cognitive tests. You will also perform computer-based tasks in which we will present you with sounds and words in the presence of different background noises while you are wearing or not wearing personal sound amplification products. During these tasks, your brain activity will be recorded by electroencephalography (EEG), a non-invasive technique with no known long-term and short-term risks. On one visit, you will perform the tasks without wearing a hearing device and on the other visit, you will perform the tasks while wearing personal sound amplification products. The devices will be provided and fitted under laboratory supervision. The study will take place in a soundproof room at the Rotman Research Institute at Baycrest Centre.

What are personal sound amplification products?

Personal sound amplification products are defined by the U.S. Food and Drug Administration as portable electronic products intended to amplify sound in the environment. They are not hearing aids designed to treat hearing loss. However, like hearing aids, they are small electronic devices that fit in the ear and amplify sound (see the image below to see what these devices look like). These products are not regulated by the Food, Drug and Cosmetic Act because they are not intended to treat, diagnose, or cure hearing loss and do not alter the structure or function of the body. Because they do not require a prescription or professional fitting, they are described as the audio version of reading glasses. *Please note that these products are not a replacement for hearing aids and their long-term use to correct hearing loss may be detrimental, as we do not yet know the extent of their risks and benefits.*

This image shows the personal sound amplification products that will be used in the study.

INCLUSION CRITERIA

You are eligible to participate in this study if you are between 60 and 90 years old, are right-handed, have English as your first language, have normal or corrected to normal vision. People who have tinnitus, learning disability, brain radiation or major medical events/surgeries (e.g., open heart surgery), neurological disorder, head injury, stroke, heart attack, depression, anxiety, psychiatric disorder or alcohol or substance abuse, and who are taking medications affecting cognition are not eligible for this study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that 100 participants will take part in this study. This study should take 1 year and 6 months to complete and the results should be known in about 2 years.

STUDY PROCEDURE

This study will consist of two visits of three (3) hours each at the Rotman Research Institute at Baycrest Centre. During the two sessions, you will complete a series of questionnaires and tasks measuring cognition, hearing and speech perception in noise:

- At the first visit only, you will be asked to complete a brief cognitive assessment, including the Montreal Cognitive Assessment (MoCA), which is a 5-minute questionnaire, and to complete computer-based tasks measuring your attention. Then you will be asked to complete questionnaires assessing your health, listening experience, depression, and anxiety symptoms. Next, hearing tests will be performed to measure your hearing status. During a test, pure tones will be sent through headphones into one ear and then into the other. This test will allow us to determine the lowest intensity at which you perceive the sounds. In a second test, you will be asked to listen to and repeat sentences presented in the presence of background noise.

- During the two visits, we will examine your brain activity while you perform computer-based tasks in which you listen and respond to different sounds or words in the presence of noise. You will be fitted with a cap containing 72 specially designed sensors to monitor

your brain activity using an electroencephalogram (EEG). Sensors will also be placed on your cheeks and forehead. In order to record a good signal of your brain activity, we will need to abrade (i.e., scrape) your scalp a little at each sensor location. Then, gel will be inserted into each sensor. Some tasks will involve responding to sounds by pressing a key on the computer keyboard. Other tasks will involve only passive listening to different words or sounds. We ask you to respond as accurately as possible and to do so in a timely manner, as some of these tasks are timed. We will give you the opportunity to practice the tasks.

- During one visit you will complete the different tasks without any hearing devices and during the other visit you will complete the tasks while wearing personal sound amplification products. The products will be provided, at no charge, for the duration of the visit. The products will be fitted under laboratory supervision.

POSSIBLE RISKS OF THE STUDY

- **Personal information:** During this study, some sensitive information will be collected. It is possible that you may feel uncomfortable or upset answering certain questions related to depression, anxiety, and health. In the event of a security breach, disclosure of this sensitive information could have consequences. However, the latter is unlikely because we follow several steps to keep your data confidential (see Confidentiality section).

- **Discomfort at the laboratory:** Some people are uncomfortable in a soundproof room because of the complete silence. Some people may develop a headache or note some mild tenderness in the scalp area due to placement of the sensors. This occurs infrequently and is not long lasting. Some participants also find some of the tasks difficult, which can cause embarrassment and stress. We do not expect you to get everything right and only ask that you give your best effort.

- **Personal sound amplification products:** Although unlikely, there is a risk of electrical shock or fire if the devices are exposed to water or mishandled. This risk is very small since

this study is conducted indoors and does not require the use of water. Persons who have or have had any of the following conditions should avoid using the devices:

- History of excessive wax build-up
- Pain or discomfort in the ear
- Fluid or drainage from the ear within the past 90 days
- Ear canal blockage, a lasting ear infection, or a plugged-up fullness feeling
- Visible deformity of the ear
- Sudden, rapid progressing, or fluctuating hearing loss within the past 90 days
- Chronic difficulty hearing
- Ringing in only one ear
- Hearing loss only in one ear that worsened in the past 90 days
- Spells of acute or chronic dizziness
- Peacemakers or defibrillators

POSSIBLE BENEFITS

You will not benefit directly from your participation in this study, but the information gathered may provide benefits to society, including providing knowledge about the effects of lost cost hearing devices that may offer an interesting avenue for improving communication skills in everyday life.

COMPENSATION

You will not be charged for your participation.

You will be compensated $15/hour for your participation in this study. You will also be compensated for travel expenses (e.g., parking or TTC).

VOLUNTARY PARTICIPATION

Your participation is voluntary. You may refuse to participate in this study at any point in time. If you decide not to participate your clinical care at Baycrest will not be impacted.

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. Information that was recorded before you withdrew will be used by

the researchers for the purposes of the study, but no information will be collected after you withdraw your permission. If you choose to withdraw from the study, you are encouraged to contact the study staff.

CONFIDENTIALY

If you decide to participate in this study, the study staff will only collect the information they need for this study. The information will only be accessible to the investigators during the study. Neither your identity nor any personal information will be available to anyone other than the investigators. No personal information will be disclosed in any resulting publication or presentation.

Your data will be stored for 10 years. The data will be deidentified in that only coded identifier will be kept with the data and the link between that coded identifier and your identity will be kept in another secure and confidential location separate from the data.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Research carried out using your data by researchers at Baycrest, or their collaborators, may lead to the development of marketable treatments, devices, new drugs, or patentable procedures. However, you will not be entitled to any benefits derived from any such commercial developments, and any benefit from commercial products will remain with Baycrest and its research partners.

DATA SHARING

In addition to the information about the study and the summary of the results which will be available on the website (http://www.clinicaltrials.gov), we also invite you to consent to have your anonymized data shared with the broader scientific community, so that other scientists can investigate further questions. The data will be shared on Scholars Portal Dataverse (https://dataverse.scholarsportal.info) or Open Neuro platform (https://openneuro.org). No personal or medical information will be shared. Only certain demographic and health information (e.g., age, gender, education, hearing status, etc.), results of tests and tasks performed in our lab, and recordings of brain activity will be shared.

You will not be re-contacted about future research uses of your data. Therefore, you are authorizing the researchers to share the data with other researchers for future research. You can still complete the study even if you do not consent to this form of data sharing.

If you do consent to sharing your data with the wider scientific community, we will further anonymize your data by replacing your participant code with a generic code that is not linked to your identity in any way. Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

STUDY RESULTS

If you are interested, we would be happy to provide you with the results of the study when they appear in press. If you would like to be informed of the results of this study, please let the study staff know by what method you would like to receive the results (e.g., mail or email).

PERSONAL TEST RESULTS

In this study, tests will be conducted to measure hearing, cognition, depression, and anxiety. These tests are used to answer research questions, not to examine your health. These tests are not a substitute for those that a professional health care would order, and it may not show problems that would be picked up by clinical tests. For this reason, your personal test results will not be shared with you.

However, in the unlikely event that we note an unexpected/worrisome finding, we will contact you to help you arrange medical follow-up to interpret the significance of the findings. By signing this consent form, you agree to releasing the test results for review. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.

COVID-19 INFORMATION REGARDING YOUR PARTICIPATION

Research site is located under the jurisdiction of Ontario public health guidelines. We are taking all safety precautions to reduce the risk of spread of COVID-19 and expect you to follow public health directives as well.

If you feel that you are from a vulnerable group with respect to COVID-19 effects (e.g., senior, immuno-compromised), please discuss your participation with the research team before

consenting. You are under no obligation to participate and nothing bad will happen if you change your mind about participating in the research.

Because you are coming onto the Baycrest campus, the following safety protocols must be followed, as per Occupational Health and Safety guidelines:

- Screening – as per requirements for persons coming onsite.
- Take appropriate precautions (e.g., face covering / cloth mask) if taking public transportation and entering public indoor spaces.
- Wash your hands upon coming onto campus / entrance to building. Hand sanitizer will be made available to you.
- Universal masking at all times on site at Baycrest.

We will be collecting personal contact information that we must retain in order to follow up with you and/or conduct contact tracing if you may have been exposed to COVID-19 in coming to Baycrest.

Contact information will be kept separate from data collected through the research study to allow for de-identification of the research data (if applicable, as detailed in the protocol).

You maintain your right to withdraw from the study at any time, including research data (if applicable). If you do withdraw, we will continue to maintain your contact information and will only give it to Occupational Health & Safety if required for contact tracing. We cannot guarantee anonymity as the personal contact information identifies you as a participant.

CONTACTS FOR FURTHER INFORMATION

If you have questions about taking part in this study, or if you suffer a research-related injury, please contact:

Claude Alain
Rotman Research Institute
Telephone: (416) 785-2500 ext. 3523
Email: calain@research.baycrest.org

If you wish to contact someone not connected with the project about your rights as a research participant, feel free to call Dr. Daphne Maurer, Chair of the Research Ethics Board at (416) 785-2500 ext. 2440

SIGNATURES

I have read the attached letter of information, and I understand the purpose of my participation and the procedures involved, as stated in this document. All my questions have been answered to my satisfaction. I understand that I can ask further questions during any stage of the study.

I understand that my participation in the study is voluntary. I may withdraw from the study at any point in time. I am aware that the study will not benefit me specifically, but knowledge will be gained that may benefit others. It has been explained to me that my identity will be kept confidential in reporting the results of the study. It has been explained to me that this study is considered a clinical trial and a description of the study and summary of the results will be available online. Neither my identity nor any personal information will be available to anyone other than the investigators. No personal and medical information will be disclosed in any resulting publication, presentation, and website. I have been given a copy of this consent form. In no way does signing this consent form waive my legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. I will be reimbursed for travel expenses; as well I will receive $15/hour for completing this study.

The study has been explained to me by: _____.
If I have any further questions, I may call Claude Alain at (416) 785-2500 ext. 3523.

Name of Participant	Signature	Date

I also understand that data collected in this study may be shared on open platforms accessible to other scientists for future projects and that I will not be contacted for the use of my data in these future projects. I am aware that I may opt out of data sharing and that this will not affect my participation in this study.

I authorize the sharing of my data on open scientific platforms:

Name of Participant	Signature	Date

Signature of Person Obtaining Consent

I personally explained the research to the participant and answered all their questions. I believe that s/he understands the information described in this document and freely consents to participate.

_____

Name of Person Obtaining Consent Signature Date